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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA, THE STATE OF )  
CALIFORNIA, THE STATE OF COLORADO, THE )  
STATE OF CONNECTICUT, THE STATE OF )  
DELAWARE, THE STATE OF FLORIDA, THE STATE )  
OF GEORGIA, THE STATE OF HAWAII, THE STATE )  
OF ILLINOIS, THE STATE OF INDIANA, THE STATE )  
OF IOWA, THE STATE OF LOUISIANA, THE STATE )  
OF MARYLAND, THE COMMONWEALTH OF )  
MASSACHUSETTS, THE STATE OF MICHIGAN, )  
THE STATE OF MINNESOTA, THE STATE OF )  
MONTANA, THE STATE OF NEVADA, THE STATE )  
OF NEW HAMPSHIRE, THE STATE OF NEW )  
JERSEY, THE STATE OF NEW MEXICO, THE )  
STATE OF NEW YORK, THE STATE OF NORTH )  
CAROLINA, THE STATE OF OKLAHOMA, THE )  
STATE OF RHODE ISLAND, THE STATE OF )  
TENNESSEE, THE STATE OF TEXAS, THE )  
COMMONWEALTH OF VIRGINIA, THE STATE )  
OF WASHINGTON, THE STATE OF WISCONSIN, )  
AND THE DISTRICT OF COLUMBIA, *EX REL.* )  
JESSICA PENELOW and CHRISTINE BRANCACCIO )

Plaintiffs, )

vs. )

JOHNSON & JOHNSON, JANSSEN PRODUCTS, LP. )

Defendants. )

CASE NO. \_\_\_\_\_

**FILED UNDER SEAL**

**JURY TRIAL DEMANDED**

**COMPLAINT PURSUANT TO  
THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *ET SEQ.*  
AND PENDENT STATE FALSE CLAIMS ACTS**

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## COMPLAINT

The *qui tam* Relators, Jessica Penelow ("Relator Penelow") and Christine Brancaccio ("Relator Brancaccio") (collectively, "Relators"), on behalf of the United States of America, The State of California, The State of Colorado, The State of Connecticut, The State of Delaware, The State of Florida, The State of Georgia, The State of Hawaii, The State of Illinois, The State of Indiana, The State of Iowa, The State of Louisiana, The State of Maryland, The Commonwealth of Massachusetts, The State of Michigan, The State of Minnesota, The State of Montana, The State of Nevada, The State of New Hampshire, The State of New Jersey, The State of New Mexico, The State of New York, The State of North Carolina, The State of Oklahoma, The State of Rhode Island, The State of Tennessee, The State of Texas, The Commonwealth of Virginia, The State of Washington, The State of Wisconsin and The District of Columbia (hereinafter referred to as the "Relator States" and collectively with the United States as the "Government Plaintiffs"), bring this action against Johnson & Johnson and Janssen Products, LP. (collectively "Defendants" or "J & J") for violations of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, as well as for violations of the following state false claims acts: The California False Claims Act, § 12650, *et seq.*; The Colorado Medicaid False Claims Act, § 25.5-4-304, *et seq.*; The Connecticut False Claims Act, § 17b-301a, *et seq.*; The Delaware False Claims and Reporting Act, § 1201, *et seq.*; The Florida False Claims Act, § 68.081, *et seq.*; The Georgia State False Medicaid Claims Act, § 49-4-168, *et seq.*; The Hawaii False Claims Act, § 661-21, *et seq.*; The Illinois False Claims Act, § 175/1, *et seq.*; The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1, *et seq.*; The Iowa False Claims Act, §685.1, *et seq.*; The Louisiana False Claims Act, § 46:437.1, *et seq.*; The Maryland False Health Claims Act, § 2-601, *et seq.*; The Massachusetts False Claims Act, Ch. 12

§ 5A, *et seq.*; The Michigan Medicaid False Claim Act, § 400.601, *et seq.*; The Minnesota False Claims Act, § 15C.01, *et seq.*; The Montana False Claims Act, § 17-8-401, *et seq.*; The Nevada Submission of False Claims to State or Local Government Act, § 357.010, *et seq.*; The New Hampshire Medicaid Fraud and False Claims Act, § 167:61-b, *et seq.*; The New Jersey False Claims Act, § 2A:32C-1, *et seq.*; The New Mexico Medicaid False Claims Act, § 27-14-1, *et seq.*; The New York False Claims Act, § 187, *et seq.*; The North Carolina Medical Assistance Provider False Claims Act, § 108A-70.10, *et seq.*; Oklahoma Medicaid Program Integrity Act §1005(A)(6); The Rhode Island False Claims Act, § 9-1.1-1, *et seq.*; The Tennessee Medicaid False Claims Act, § 71-5-181, *et seq.*; The Texas Medicaid Fraud Prevention Act, § 36.001, *et seq.*; The Virginia Fraud Against Taxpayers Act, § 8.01-216.1, *et seq.*; The Washington Health Care False Claim Act, § 48.80.010, *et seq.*; The Wisconsin False Claims for Medical Assistance, Wis. Stat. § 20.931, *et seq.*; The District of Columbia False Claims Act, § 2-381.01, *et seq.* (hereinafter referred to as the “State False Claims Acts”), to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts. The relevant state and federal programs that paid for prescriptions of Prezista and Intelence based on J & J’s fraudulent course of conduct are referred to herein as the Government Healthcare Programs.

### **SUMMARY OF THE ACTION**

1. This case involves the illegal, off-label marketing of two J & J drugs, Prezista (darunavir) and Intelence (etravirine), both antiretroviral (ARV) drugs used to treat patients infected with HIV/AIDS. J & J and one of its pharmaceutical subsidiaries, Janssen Products, LP (“Defendants” or “J & J”), are companies with a long history of prior misconduct involving off-label promotion of its drugs, including the blockbuster anti-psychotic drug, Risperdal, the

epilepsy drug, Topamax, and the heart failure drug, Natrecor. Despite this history, Defendants continue to market and sell the ARV drugs Prezista and Intelence with misleading, off-label messages, thereby knowingly causing physicians to prescribe the drugs, and the Government Plaintiffs to reimburse for the drugs, in violation of the Federal and State False Claims Acts and the federal Anti-Kickback Statute.

2. As set forth herein, in selling and promoting Prezista, J & J, through its sales representatives and managers, routinely delivered false and misleading messages to physicians by: 1) promoting Prezista as “lipid-neutral” contrary to its FDA-approved label which indicates a side effect of the drug is an increase in cholesterol and triglycerides; and 2) misstating Prezista’s superiority, efficacy and potency based on the uniqueness of its “binding affinity.”

3. With respect to promoting Prezista as “lipid-neutral,” J & J falsely and misleadingly claimed that the drug would *not* affect or increase a patient’s cholesterol or triglyceride levels, which is directly contradicted by the FDA-approved label for Prezista. Prezista’s label shows that the drug has a significant negative effect on lipids, including cholesterol and triglycerides. The label specifically lists as serious adverse drug reactions the following: high cholesterol (hypercholesterolemia), high triglycerides (hypertriglyceridemia) and an increase in LDL (“bad” cholesterol).

4. This misleading promotion, which began in 2006 and continues through the present, is significant because heart disease caused by high cholesterol and triglycerides is a real safety threat and concern for HIV/AIDS patients. J & J’s promotion of Prezista as “lipid-neutral” falsely minimizes this threat. Further, the two scientific studies on which J & J relies to support its “lipid-neutral” promotion are not part of the FDA-approved label and are of questionable scientific value.

5. In addition to misleadingly promoting Prezista as lipid-neutral, beginning in and around February 2007 and continuing through the present, Defendants' sales representatives and managers have made unsupported claims regarding Prezista's superiority, efficacy and potency based on its purported superior "binding affinity." "Binding affinity" refers to the way in which Prezista works in a patient's body. Prezista belongs to the Protease Inhibitor ("PI") class of drugs. All PI drugs work the same way by binding to the active site of the HIV protease (an enzyme critical for viral replication) and inhibiting it from replicating.

6. Defendants misleadingly claimed that compared with other PI drugs, Prezista is a stronger, more potent and efficacious drug with superior binding affinity which would prevent the HIV virus from mutating, and thus prevent drug resistance. However, J & J's claims of superior binding affinity are misleading because they are based on a clinical study which is not included in the drug's FDA-approved labeling and is of limited scientific value because it was done by a J & J subsidiary, Tibotec, whose scientists conducted the study, Tibotec funded the study and the study was performed in a lab, and not on HIV-infected patients. Further, J & J had previously been instructed by the FDA to *remove* information regarding superior binding affinity from early Prezista promotional materials because the claim was not adequately supported.

7. With regard to Intelence, beginning in 2008 and continuing through the present, Defendants promoted Intelence as safe and effective for *once-daily dosing* contrary to the FDA-approved label stating that the drug *must be taken twice a day*. The dosage information in the drug's package insert specifically states that Intelence (one 200 mg tablet or two 100 mg tablets) should be taken *twice daily*.

8. Despite these explicit dosing instructions, Defendants' sales representatives and managers made false and misleading statements to physicians that patients could safely and



effectively take Intelence once a day. Intelence's label states that patients *should not* take 400mg of Intelence at one time if they miss a dose by more than 6 hours. Defendants have not established to the satisfaction of the FDA that Intelence is safe and effective for once a day dosing and promoted Intelence off-label for once a day dosing in order to increase sales and compete with other more convenient ARV drugs which only need to be taken once a day. Once-daily dosing is easier for patients to follow and more appealing, but if a patient does not carefully follow the FDA-indicated dosing drug regimen, their HIV viral load can increase, potentially weakening the drug's ability to fight the disease.

9. J & J delivered these misleading messages regarding Prezista and Intelence during sales calls, dinner programs and speaker programs nationwide. Furthermore, as alleged herein, J & J's payments to speakers at the dinner programs and speaker programs amounted to kickbacks in violation of the Anti-Kickback Statute. These speakers were paid an increasing honorarium based upon their market share of the drugs. J & J calculated market share as the percentage of J & J drugs that a doctor prescribes in a class (Prezista belongs to the PI class of drugs and Intelence belongs to the NNRTI class) compared to non-J & J drugs in that class. Prescribing speakers with a high market share would be paid \$2,500 per program (as opposed to \$2,000) and a speaker with a low market share would ultimately be dismissed from the speaker bureau.

10. The amount of these kickbacks was material to doctors. For example, Dr. Donald Kaminsky, a physician who practices in Manhattan, stated to Relator Penelow that he wouldn't be able to pay for his mortgage without the honorarium he receives for his talks from J & J. Moreover, Dr. Kaminsky told Relator Penelow that he was willing to say whatever J & J and Nancy Barnett (a J & J Key Account Manager) told him to say, even if such messages were off-label.

11. By selling and promoting Prezista and Intelence off-label, Defendants knowingly and misleadingly influenced physicians' medical judgments in deciding which drugs to prescribe. In treating HIV/AIDS patients, physicians typically prescribe a combination or "cocktail" of ARV drugs. Different factors such as the drug's effect on a patient's lipids or the dosing regimen required (twice-a-day vs. once-a-day) are important considerations. Defendants knowingly misled doctors to increase profits at the expense of the Government Plaintiffs by engaging in fraudulent and off-label marketing.

12. At all relevant times, Defendants were fully aware that the Government Plaintiffs reimbursed a substantial portion of Prezista and Intelence prescriptions. A significant percentage of HIV/AIDS patients are on Medicare/Medicaid. In sum, through the illegal conduct detailed herein, Defendants caused untold numbers of claims tainted by the off-label marketing, misbranding, and kickback schemes to be submitted to the Government Plaintiffs for reimbursement.

13. While Relators currently have some documentary evidence of this off-label marketing scheme, many documents detailing J & J's illegal conduct previously on Relators' work laptop computers were destroyed by J & J in November 2010 when J & J IT personnel requested that Relators give them their computers and later returned the computers scrubbed of all data.

#### **THE PARTIES**

14. Defendant Johnson & Johnson is a corporation organized under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. Johnson & Johnson is a holding company that owns more than 250 operating companies conducting business in virtually all countries of the world. Johnson & Johnson's businesses operate in three segments:

Consumer, Pharmaceutical, and Medical Devices and Diagnostics. At all relevant times herein, J & J's wholly owned subsidiary, Janssen Products, LP, marketed and sold Prezista and Intelence through an illegal, off-label marketing campaign in this District and nationwide.

15. Defendant Janssen Products, LP ("Janssen") is a subsidiary of Johnson & Johnson and incorporated in New Jersey with its principal place of business in Titusville, NJ. At all relevant times herein, Janssen marketed and sold Prezista and Intelence through an illegal, off-label marketing campaign in this District and nationwide.

16. The United States is a plaintiff to this action. The United States brings this action on behalf of the Department of Health and Human Services ("DHHS") and the Centers for Medicare and Medicaid Services ("CMS") which administer the Medicare and Medicaid Programs.

17. The State of California ("California") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in California and were covered Medicaid benefits under California's Medi-Cal Program.

18. The State of Colorado ("Colorado") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Colorado and were covered Medicaid benefits under Colorado's Medicaid Program.

19. The State of Connecticut ("Connecticut") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Connecticut and were covered Medicaid benefits under Connecticut's Medicaid Program.

20. The State of Delaware (“Delaware”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Delaware and were covered Medicaid benefits under Delaware’s Medicaid Program.

21. The State of Florida (“Florida”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Florida and were covered Medicaid benefits under Florida’s Medicaid Program.

22. The State of Georgia (“Georgia”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Georgia and were covered Medicaid benefits under Georgia’s Medicaid Program.

23. The State of Hawaii (“Hawaii”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Hawaii and were covered Medicaid benefits under Hawaii’s Medicaid Program.

24. The State of Illinois (“Illinois”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Illinois and were covered Medicaid benefits under Illinois’ Medicaid Program.

25. The State of Indiana (“Indiana”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Indiana and were covered Medicaid benefits under Indiana’s Medicaid Program.

26. The State of Iowa (“Iowa”) is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Iowa and were covered Medicaid benefits under Iowa’s Medicaid Program.

27. The State of Louisiana ("Louisiana") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Louisiana and were covered Medicaid benefits under Louisiana's Medicaid Program.

28. The State of Maryland ("Maryland") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Maryland and were covered Medicaid benefits under Maryland's Medicaid Program.

29. The Commonwealth of Massachusetts ("Massachusetts") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Massachusetts and were covered Medicaid benefits under Massachusetts' Medicaid Program.

30. The State of Michigan ("Michigan") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Michigan and were covered Medicaid benefits under Michigan's Medicaid Program.

31. The State of Minnesota ("Minnesota") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Minnesota and were covered Medicaid benefits under Minnesota's Medicaid Program.

32. The State of Montana ("Montana") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Montana and were covered Medicaid benefits under Montana's Medicaid Program.

33. The State of Nevada ("Nevada") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Nevada and were covered Medicaid benefits under Nevada's Medicaid Program.

34. The State of New Hampshire ("New Hampshire") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New Hampshire and were covered Medicaid benefits under New Hampshire's Medicaid Program.

35. The State of New Jersey ("New Jersey") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New Jersey and were covered Medicaid benefits under New Jersey's Medicaid Program.

36. The State of New Mexico ("New Mexico") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New Mexico and were covered Medicaid benefits under New Mexico's Medicaid Program.

37. The State of New York ("New York") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in New York and were covered Medicaid benefits under New York's Medicaid Program.

38. The State of North Carolina ("North Carolina") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in North Carolina and were covered Medicaid benefits under North Carolina's Medicaid Program.

39. The State of Oklahoma ("Oklahoma") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Oklahoma and were covered Medicaid benefits under Oklahoma's Medicaid Program.

40. The State of Rhode Island ("Rhode Island") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Rhode Island and were covered Medicaid benefits under Rhode Island's Medicaid Program.

41. The State of Tennessee ("Tennessee") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Tennessee and were covered Medicaid benefits under Tennessee's Medicaid Program.

42. The State of Texas ("Texas") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Texas and were covered Medicaid benefits under Texas' Medicaid Program.

43. The Commonwealth of Virginia ("Virginia") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Virginia and were covered Medicaid benefit under Virginia's Medicaid Program.

44. The State of Washington ("Washington") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Washington and were covered Medicaid benefits under Washington's Medicaid Program.



45. The State of Wisconsin ("Wisconsin") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in Wisconsin and were covered Medicaid benefits under Wisconsin's Medicaid Program.

46. The District of Columbia ("DC") is a Plaintiff to this action. Throughout the relevant time periods specified herein, Prezista and Intelence were provided to Medicaid recipients in DC and were covered Medicaid benefits under DC's Medicaid Program.

47. Relator, Jessica Penelow, is a citizen of the United States and resides at 30 Heron Road, Livingston, New Jersey 07039. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1) and the relevant provisions of the State False Claims Acts. Relators bring this action on behalf of the United States for violations of the Federal False Claims Act and on behalf of each Relator State named herein for violations of its respective State False Claims Act.

48. Relator Penelow graduated from Florida Atlantic University in 1998 with a B.S. in healthcare administration and management and from St. Joseph's College in 2012 with an MBA. Relator started as a Senior Virology Sales Consultant at Tibotec Therapeutics ("Tibotec") in 2006 and continues to hold that position today. Tibotec was a subsidiary of Johnson & Johnson and changed its name to Janssen in 2011. She currently markets four HIV drugs, Edurant, Complera, Prezista and Intelence, to doctors on the Lower East Side of Manhattan. Through her continued employment at J & J and her interactions with both doctors and the Defendants' sales representatives and managers that solicited the doctors, Relator has uncovered the False Claims Act violations against J & J detailed herein.

49. Relator, Christine Brancaccio, is a citizen of the United States and resides at 14 White Hall Court, Holbrook, New York 11741. Relator has standing to bring this action



pursuant to 31 U.S.C. §3730(b)(1) and the relevant provisions of the State False Claims Acts. Relator brings this action on behalf of the United States for violations of the Federal False Claims Act and on behalf of each Relator State named herein for violations of its respective State False Claims Act.

50. Relator Brancaccio graduated from Dowling College in 1984 with a B.B.A. in Business Administration. Relator started as a Senior Virology Sales Representative with Ortho Biotech in 2003, which was a subsidiary of J&J, where she sold the HIV drug Procrit. Since 2006, she has worked for J & J as a Senior Virology Sales Representative responsible for marketing Prezista, Intelence, Edurant and Complera to providers on Long Island and Queens. Through her continued employment at J & J and her interactions with both doctors and the Defendants' sales representatives and managers that solicited them, Relator has uncovered the False Claims Act violations against J & J detailed herein.

### **JURISDICTION AND VENUE**

51. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331, 1345, and is not barred by § 3730(e). The information upon which these allegations are based was voluntarily provided by Relators to the Federal Government prior to filing the Complaint pursuant to 31 U.S.C. §§ 3730(e)(4)(B) and 3730(b)(2).

52. Venue in the District of New Jersey is appropriate under 31 U.S.C. § 3732(a) and sufficient contacts exist for jurisdiction in that Defendant conducts business and sells its pharmaceuticals, including Intelence and Prezista, in the District of New Jersey. Such drugs, as Defendant knows, (1) have been and continue to be supplied to government health care program

recipients, including Medicare and Medicaid recipients and (2) have been and continue to be the subject of claims for reimbursement by drug providers to government health care programs.

53. A copy of the Complaint and written disclosures of substantially all material evidence and information in both Relators' possession were served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, prior to the filing of the Complaint *in camera* and under seal by delivering a copy of the Complaint, material evidence and information to the United States Attorney General, the United States Attorney for the District of New Jersey and by sending a copy of the Complaint, material evidence and information by certified mail to the Attorneys General for California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, and the District of Columbia; and to the Chief Financial Officer of the Florida Department of Financial Services.

## **BACKGROUND**

### **I. THE APPLICABLE LAW**

#### **A. The Prohibition Against Misbranding and Marketing Drugs for Off-Label Uses**

##### **1. FDA Laws and Regulations**

54. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed or sold in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §§ 355(a) & (d).

55. In order for FDA approval of a new drug, the drug manufacturer must present substantial evidence of efficacy through adequate and well-controlled studies. 21 C.F.R. § 314.50(d). FDA regulations specify the characteristics of what constitutes an adequate and well-controlled study. Noting that these characteristics “have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation[.]” the regulations detail the following requirements, *inter alia*: a clear statement of the objective of the investigation and a summary of the methods of analysis actually used; a study design “that permits a valid comparison with a control” group; and adequate measures to minimize bias on the part of the subjects, observers and analysts of the data. *Id.* § 314.126(a), (b).

56. The FDA does not approve a drug for treatment of a disease in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved uses are called the “indications” for which the drug may be prescribed. For each approved indication, the FDA will specify particular dosages and dosage frequency determined to be safe and effective. In approving a drug for a given indication, the FDA also approves the language of the product’s label (the package insert or prescribing information).

57. The FDCA defines labeling very broadly, to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m) (2006).

58. Promotional materials that do not qualify as labeling are regulated as advertising by the FDA. Although neither advertisement nor advertising is defined in the FDCA, section 352(n) and the implementing regulations demonstrate the broad nature and scope of information

regulated as “advertising.” Advertisements subject to section 352(n) include those “in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.” Thus, in combination with its authority over promotional labeling, the FDA’s regulatory oversight of prescription drug marketing extends to practically every type of material and media.

59. Use of an approved drug for any purpose other than those indications specifically approved by the FDA is referred to as an “off-label” use. Off-label uses include treating a condition not indicated on the label, treating the indicated condition at a different dosage or dosage frequency from the label’s recommended dose, or treating a different patient population than those approved by the FDA.

60. Once a drug is approved as safe and effective for one indication, the FDA does not prohibit doctors from prescribing the drug for off-label uses. This is consistent with the FDA’s mission to regulate drugs without interfering with the practice of medicine and doctors’ discretion in treating their patients.

61. Although physicians may prescribe drugs for non-FDA-approved uses, the law prohibits drug manufacturers from selling a drug that is misbranded. 21 U.S.C. § 331.

62. A drug is considered “misbranded” if its labeling is “false or misleading in any particular.” 21 U.S.C. § 352(a). A manufacturer illegally “misbrands” a drug if the drug’s labeling, *inter alia*, describes intended uses for the drug that have not been approved by the FDA, or if there are unsubstantiated claims of efficacy or safety.

63. Further, an advertisement for a drug (as defined above) is “false, lacking in fair balance, or otherwise misleading... if it.”

(i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience;

\* \* \*

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;

\* \* \*

(iv) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;

\* \* \*

(x) Uses literature, quotations, or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim;

21 C.F.R. §202.1.

64. In sum, the FDCA prohibits drug companies from promoting approved drugs for unapproved uses or from making misleading claims as to the drug's safety or effectiveness. *See* 21 U.S.C. §§ 331, 352, 355(d). This regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body: the FDA.

65. The Pharmaceutical Research and Manufacturers of America ("PhRMA"), the industry association of drug companies, has guidelines governing drug marketing, the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"). In the section titled "Basis of Interactions:" the Code states that "[p]romotional materials provided to Healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make

claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.” PhRMA Code, Section 1.

## 2. FDA Guidance on Good Reprint Practices

66. As alleged below, Defendants relied on several unsubstantiated scientific studies in promoting Prezista as lipid-neutral and with superior “binding affinity.” In doing so, in addition to unlawful off-label promotion and misbranding Defendants violated the tenants of the FDA’s “Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,” (“Reprint Guidance”).

67. The Reprint Guidance reflects the FDA’s “current views on the dissemination of medical journal articles and medical or scientific reference publication on unapproved uses of approved drugs.” *Available at* <http://www.fda.gov/oc/op/goodreprint.html> (Jan. 2009). The Guidance applies if a manufacturer is distributing scientific and medical information concerning safety and effectiveness of a non-FDA-approved use for a drug.

68. Among other criteria, the Guidance states that the information contained in the scientific or medical journal article “should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts.” Further, the type of scientific or medical journal article distributed should be “peer-reviewed” and not “in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.”

69. In addition, there are several requirements regarding the manner in which to disseminate the scientific and medical information. The scientific or medical journal article

should be accompanied by the approved labeling for the drug, and should be distributed separately from promotional material. If it is being distributed by a sales representative, it “should not be the subject of discussion between the sales representative and the physician during the sales visit.” (emphasis added).

**B. The Prohibition Against Kickbacks**

**1. The Anti-Kickback Statute**

70. As alleged below, J & J’s payments to high-prescribing physicians to speak at dinner and speaker programs amounted to kickbacks in violation of the “Anti-Kickback” Statute (“AKS”), 42 U.S.C. §1320a-7b(b)(2)(B) and relevant state Anti-Kickback Statutes. The AKS prohibits the payment of any remuneration to any person in order to induce that person to “purchase, lease, order, arrange for or recommend purchasing, leasing or ordering any good, facility, service or item” for which reimbursement may be made under a Federal health program. Anyone found guilty of offering or paying kickbacks in violation of the Anti-Kickback Statute shall be guilty of a felony.

71. Specific intent is not required to establish a violation of the AKS. That is, “a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS].” 42 U.S.C. §1320(a)-7b(h)).

72. A “Federal health care program” is defined at 42 U.S.C. §1320a-7b(f) as any plan or program providing health benefits funded, whether directly or indirectly, by the United States Government. The Anti-Kickback Statute applies to claims for reimbursement of Prezista and Intelence prescriptions submitted to the Government Healthcare Programs, including Medicare and Medicaid.



## 2. Relevant Guidance

73. The OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (the OIG Guidance), also provides direction as to what constitutes a violation of AKS. The OIG Guidance states that “[a]ny time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer’s product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.”

74. The government determines whether the arrangement between a pharmaceutical manufacturer and a physician violates the AKS “in light of the totality of all facts and circumstances, bearing in mind the following facts, among others:”

- Nature of the relationship between the parties. What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer?
- Manner in which the remuneration is determined. Does the remuneration take into account, directly or indirectly, the volume or value of business generated (e.g., is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer’s product)?
- Value of the remuneration. Is the remuneration more than trivial in value?
- Potential federal program impact of the remuneration. Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?
- Potential conflicts of interest. . . . If the remuneration relates to the dissemination of information, **is the information complete, accurate, and not misleading?**

68 Fed. Reg. at 23737 (emphasis added).

75. In light of those factors, payments to physicians described herein constitute unlawful kickbacks.



### **3. The PhRMA Code**

76. J & J is a member of PhRMA and a signatory to the PhRMA Code, PhRMA's guidelines governing drug marketing.

77. As alleged below, J & J delivered misleading and off-label messages to healthcare professionals at, *inter alia*, dinner and speaker programs nationwide. The PhRMA Code, revised July 2008, includes the following applicable section prohibiting this conduct:

- Section 7 – “Speaker Programs and Speaker Training Meetings”: When a pharmaceutical company hires a healthcare professional to help educate other healthcare professionals about the company's products, the company is responsible and accountable for the content of the speech. Speakers should “clearly identify the company that is sponsoring the presentation... and that the speaker is presenting information that is consistent with FDA guidelines.” “Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communication skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.”

## **II. THE RELEVANT GOVERNMENT HEALTH CARE PROGRAMS**

78. The government health care programs referenced herein include Medicaid and Medicare, discussed more fully in Sections A and B below, and encompass any health care plan or program that provides health benefits, whether funded directly, in whole or in part, by the United States or the Relator States such as, for example, ADAP (AIDS Drug Assistance Program), the Ryan White CARE Act and HDAP (HIV Drug Assistance Program in Massachusetts).

### **A. The Medicaid Program**

79. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the “Medicaid Program”). Enacted in 1965, the Medicaid Program

functions as a jointly-funded cooperative undertaking between the Federal and State Governments. Each State administers its own Medicaid program, but the State's programs are governed by Federal statutes, regulations and guidelines.

80. The federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage, is based on a State's per capita income compared to the national average. During the relevant time period, the federal portion consisted of a minimum of 50% up to a maximum of roughly 80%. For 2008, the federal portion of Medicaid spending on HIV/AIDS was estimated to be \$4.1 billion and the total state spending to be \$3.4 billion. *See* The Henry J. Kaiser Family Foundation, *HIV/AIDS Policy Fact Sheet*, Feb. 2009.

81. The States (and the District of Columbia) are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for Federal funds for Medicaid expenditures. 42 U.S.C. § 1396a(a)(30)(A).

82. Benefits for drugs are optional, but all States, including those named herein, have opted to provide Medicaid drug reimbursement coverage.

83. Medicaid drug reimbursement coverage is limited to "covered outpatient drugs" which are drugs used for "a medically accepted indication." A "medically accepted indication" means any use or indication which is approved by the FDA or which is supported by one or more citations in certain drug compendia. *See* 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i). The relevant drug compendia are: American Hospital Formulary Service (AHFS) Drug Information, United States Pharmacopeia-Drug Information (USP DI) (or its successor publications) and the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i).

84. At all relevant times, the cost of providing Intelence and Prezista for on-label uses to Medicaid recipients was covered by many States' Medicaid Programs, including each of the

Medicaid Programs for the Relator States. At all relevant times, the cost of providing Intelence and Prezista for off-label uses to Medicaid recipients was not covered by Medicaid because the off-label uses were neither approved by the FDA nor supported by one or more citations included in any of the specified drug compendia.

85. Many individuals with HIV/AIDS become indigent as a result of not being able to work due to illness. There were an estimated 200,000 to 240,000 AIDS patients on Medicaid, as of February 2009. *See* The Henry J. Kaiser Family Foundation, *HIV/AIDS Policy Fact Sheet*, Feb. 2009. Medicaid is the “single largest source of coverage for people with HIV in the United States.” *Id.*

**B. The Medicare Program**

86. The Medicare Program is the federally financed health insurance system for persons who are aged 65 and over, for those who are disabled and for those suffering from end-stage renal disease. On January 1, 2006, the Medicare Part D prescription drug benefit went into effect. Medicare Part D subsidizes the cost of prescription drugs for Medicare beneficiaries. *See* Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*

87. According to the Kaiser Family Foundation, Medicare spends \$4.5 billion on HIV drugs.

88. Part D covers the cost of FDA-approved prescription drugs used for “a medically accepted indication.” *See* 42 U.S.C. §§ 1395w-102(e)(1), 1395w-151(a)(2). Just as in the Medicaid Program, for Medicare reimbursement, a “medically accepted indication” means any use or indication which is approved by the FDA or which is supported by one or more citations in certain drug compendia: AHFS Drug Information, USP DI (or its successor publications) and the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i). The

relevant drug compendia are the same as those for Medicaid: AHFS Drug Information, USP DI (or its successor publications) and the DRUGDEX Information System. *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i). In sum, Part D drug coverage excludes drugs not approved by the FDA, and those not for use for a medically accepted indication.

89. The Medicare Part D prescription drug benefit is offered by private prescription drug plans (PDPs) and Medicare prescription drug plans (MA-PDs). Medicare beneficiaries have a choice among many different plans in each state. Medicare reimburses the private plans for its coverage of Medicare beneficiaries.

90. At all relevant times herein, the costs of Prezista and Intelence were covered Medicare drugs when provided to a Medicare beneficiary for use as indicated on the drugs' label. Prezista and Intelence were not covered Medicare drugs where they were misbranded and/or prescribed off-label.

91. Many AIDS patients who are under 65 nonetheless qualify for Medicare coverage because they are disabled. In addition, many low-income and disabled AIDS patients are dual eligibles – those who qualify for both Medicare and Medicaid. In the case of dual eligibles, Medicare is the primary source of drug coverage.

### **III. BACKGROUND REGARDING HIV/AIDS & TREATMENT**

92. As explained by the National Institutes of Health, AIDS (acquired immunodeficiency syndrome) was first reported in the United States in 1981 and has since become a major worldwide epidemic. AIDS is caused by HIV (human immunodeficiency virus). By killing or damaging the cells of the immune system, HIV progressively destroys the body's immune system and ability to fight infections and cancer. The most obvious effect of HIV infection is a decline in the number of CD4 cells found in the blood, an integral part of the

immune system's key infection fighters. The virus slowly disables or destroys these cells. The term AIDS applies to the most advanced stages of HIV infection.

93. There are currently six different classes of antiretroviral (ARV) drugs that stop the HIV replication process at different stages of development: entry inhibitors, fusion inhibitors, nucleoside/nucleotide reverse transcriptase inhibitors ("NRTIs"), non-nucleoside reverse-transcriptase inhibitors ("NNRTIs"), integrase inhibitors ("II") and protease inhibitors ("PIs"). Prezista belongs to the PI class of drugs and Intelence is an NNRTI.

94. Guidelines for AIDS treatment are published by the Department of Health and Human Services (the DHHS Guidelines). At all relevant times herein, the DHHS Guidelines have recommended that patients take a combination of three or more medications in a regimen called Highly Active Antiretroviral Therapy (HAART). For people taking HIV antiretroviral drugs for the first time, a combination regimen generally consists of two NRTIs and one active drug from one of the following classes: NNRTI, PI (generally boosted with ritonavir), II, or entry inhibitor.

95. HAART recommends taking three drugs at once because clinical studies show that HIV becomes resistant when only one drug is used. When a three drug cocktail is prescribed, if the HIV mutates to become resistant to one drug, the other two drugs may prevent that mutant HIV strain from replicating: this makes it more difficult for a resistant HIV strain to become dominant in the body. Furthermore, the chances are relatively low that HIV will develop three mutations that create resistance to three drugs and still maintain the ability to reproduce. By attacking HIV in different ways, the viral load is reduced and the chance of HIV developing resistance is decreased. Therefore, it is critical that patients take a cocktail of three drugs that are effective in slowing HIV replication in the body.

96. Adherence to a treatment regimen is very important. AIDS treatment regimens can be complicated in that they involve taking many pills at different times of the day with or without food. Correctly following a regimen can be difficult for many people, especially those who are sick or suffering side effects. Nonetheless, adherence is important because it impacts how well the drug works (if you miss a dose, HIV has an opportunity to replicate) and helps prevent drug resistance (if you miss a dose, you may develop strains of HIV that are resistant to ARV drugs). “Adherence to antiretroviral therapy (ART) has been correlated strongly with HIV viral suppression, reduced rates of resistance, an increase in survival, and improved quality of life.” *Limitations to Treatment Safety and Efficacy: Adherence to Antiretroviral Therapy*, <http://www.aidsinfo.nih.gov/Guidelines/HTML/1/adult-and-adolescent-treatment-guidelines/30/> (last visited Sept. 6, 2012).

97. Where an initial HIV drug regimen fails, HAART recommends changing the drug regimen as soon as possible with three new fully effective antiretroviral drugs. HAART states:

Once virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations. Ideally, a new ARV regimen should contain at least two, and preferably three, fully active drugs on the basis of drug treatment history, resistance testing, or new mechanistic class.

98. HAART notes that switching a patient who has experienced failure on one drug combination to different drugs may not be sufficient because a mutation may make HIV resistant to multiple drugs that have similar mechanisms of action. HAART states: “Because of the potential for drug-class cross resistance that reduces drug activity, using a ‘new’ drug that a patient has not yet taken may not mean that the drug is fully active.”

#### **IV. J & J'S PRIOR HISTORY OF ILLEGAL, OFF-LABEL MARKETING**

99. J & J created fraudulent, off-label marketing schemes that involved three of J & J's largest drugs – Risperdal, Topamax, and Natrecor – at the same time that it orchestrated the off-label marketing of Prezista and Intelence.

100. In 1993, the FDA approved Risperdal to treat schizophrenia. The drug was not tested on the elderly. Nevertheless, J & J engaged in a fraudulent, off-label marketing campaign promoting the use of the drug to treat dementia in elderly patients. The illegal marketing campaign generated billions of dollars in sales for J & J and continued despite numerous FDA warning letters concerning the illegal marketing of Risperdal. The illegal marketing campaign only ceased after investigations by the U.S. Attorney's Office in Philadelphia, the New York State Attorney General, the Texas State Attorney General, the California State Attorney General, and the Louisiana State Attorney General resulted in over \$4 billion in penalties and settlements.

101. Topamax, a J & J drug, was approved in 1996 to treat epilepsy and migraine headaches. J & J developed an extensive program dedicated to the aggressive promotion of Topamax for a laundry list of ailments and diseases– including pediatric bipolar disorder and alcohol addiction – for which it was not indicated and for which it had not received FDA approval. J & J trained its sales force to mislead physicians into prescribing the drug for off-label uses by referring to non-existent “scientific evidence” or sometimes to evidence that was significantly scientifically flawed. In April 2010, a J & J subsidiary pled guilty to violating the FDCA and paid a \$6.14 million criminal fine for the illegal promotion of Topamax for psychiatric uses. At the same time, a J & J subsidiary resolved two whistleblower claims by agreeing to pay \$75.37 million for its illegal promotion of Topamax for off-label uses.



102. In 2001, the FDA approved Natrecor for the limited and specific use of intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. By definition, this condition is an emergency situation that does not occur on a scheduled basis. Scios, Inc., a J & J subsidiary, developed an unlawful marketing plan around promoting Natrecor for regularly scheduled outpatient infusions. J & J continued the illegal marketing campaign even after convening a panel of 10 cardiologists in 2005 who found that Natrecor should be strictly limited to on-label uses.

103. In October of 2011, the U.S. Justice Department announced that Scios pled guilty to a misdemeanor and agreed to pay an \$85 million criminal fine to settle criminal charges related to the marketing of Natrecor for off-label uses.

## V. THE FALSE CLAIMS ACT SCHEME

### A. J & J's False and Misleading Messaging in Promoting Prezista

104. In selling and promoting Prezista, Defendants routinely delivered false and misleading messages by:

- promoting Prezista as “lipid-neutral” contrary to its FDA-approved label; and
- overstating Prezista’s superiority, efficacy and potency based on the uniqueness of its “binding affinity.”

Sections 1 and 2 below explain these two false and misleading messaging campaigns and also give specific examples of oral misrepresentations made to physicians about Prezista.

#### 1. J & J's Promotion of Prezista as “Lipid-neutral” Misleadingly Conceals a Dangerous Side Effect of the Drug

105. Beginning in 2006 and continuing through the present, J & J sales representatives and managers have falsely and misleadingly promoted Prezista as “lipid-neutral,” meaning that the drug would *not* affect or increase a patient’s cholesterol or triglyceride levels, contrary to



Prezista's label. This is significant because heart disease caused by high cholesterol and triglycerides is a real threat for AIDS patients. Defendants' promotion of Prezista as "lipid-neutral" falsely minimizes this threat and is directly contradicted by Prezista's label which in fact shows that Prezista *increases* lipids in patients. Further, the two scientific studies on which J & J relied are not part of the FDA-approved label and are of questionable scientific value. J & J was also motivated to promote Prezista as lipid-friendly in order to compete with another PI drug, Reyataz, which in fact does not have an effect on a patient's lipid levels.

**a. Serious Risk of Heart Disease for HIV/AIDS Patients**

106. Defendants' off-label promotion of Prezista as "lipid-neutral" misleadingly minimizes the very serious risk of cardiovascular disease for HIV/AIDS patients. With the number of available treatment options, many HIV/AIDS patients are living longer lives and not dying from the HIV/AIDS virus, but rather from cardiovascular events such as heart attack or stroke. In addition to the increased risk of heart problems as patients age, it is thought that HIV/AIDS itself may increase a patient's lipid levels. Also, some HIV/AIDS drugs, in particular Protease Inhibitor drugs, increase lipid levels which can lead to heart disease. Further, many PI drugs, including Prezista, are used in combination with the booster drug, Norvir (ritonavir), which is known to increase lipid levels in HIV/AIDS patients.

107. The risk of heart disease caused by high cholesterol is further exacerbated by the fact that cholesterol-lowering drugs may not work for HIV/AIDS patients. That is, high cholesterol caused by boosted Protease Inhibitor drugs (such as Prezista boosted with Norvir) may "be refractory to diet, exercise and hypolipidemic drugs." See <http://hivmanagement.org/pi/html>. In other words, patients with high cholesterol caused by

their HIV/AIDS drug treatment regimen unfortunately may not be able to lower their cholesterol levels by eating healthier, exercising more or taking cholesterol-lowering drugs.

108. By way of background, cholesterol or lipid levels are measured by analyzing a patient's blood for the following:

- high density lipoprotein (HDL or "good" cholesterol);
- low density lipoprotein (LDL or "bad" cholesterol);
- total cholesterol; and
- triglycerides

109. Cholesterol and triglycerides are two forms of lipids or fatty deposits that circulate in a patient's blood stream. They are necessary for building healthy cells and providing energy for tissues to function. However, high cholesterol (hypercholesterolemia), in particular high LDL cholesterol, or high triglycerides (hypertriglyceridemia) cause heart disease when the fatty deposits clog the patient's arteries. This makes it difficult for blood to flow through the arteries and may lead to a heart attack, stroke or other serious heart condition.

**b. J & J's Promotion of Prezista as "Lipid-neutral" is Contradicted by Prezista's Label**

110. Defendants' marketing of Prezista as "lipid-neutral" is directly contradicted by the FDA-approved label for Prezista. Prezista's label shows that the drug has a significant negative effect on lipids, including cholesterol and triglycerides. The label specifically lists as serious adverse drug reactions ("ADRs") the following: high cholesterol (hypercholesterolemia), high triglycerides (hypertriglyceridemia) and an increase in LDL ("bad" cholesterol).

111. The label shows a significant percentage of patients on Prezista whose lipid levels increased *beyond* the safe or optimal levels which are as follows:

- Total Cholesterol – Below 200 mg/dL

- LDL Cholesterol – Below 100 mg/dL
- Triglycerides – Below 150 mg/dL<sup>1</sup>

112. Prezista caused a significant percentage of patients' lipid levels to increase to high or very high. Specifically, of the naïve patients taking Prezista, 24% developed high total cholesterol, 23% developed high LDL cholesterol and 6% developed high triglycerides. *See* Prezista, Full Prescribing Information, Table 6, pg 6. For treatment-experienced patients taking Prezista, the cholesterol profile was worse - 35% of patients developed high total cholesterol, 22% developed high LDL cholesterol and 20% developed high triglycerides. *See* Prezista, Full Prescribing Information, Table 8, pg 7. These results were based on robust clinical studies detailed in the label and discussed more fully below.

113. By contrast, the label for Reyataz, Prezista's chief competitor, does not list high cholesterol as a serious adverse drug reaction. To the contrary, Reyataz's label contains studies that show that Reyataz does not significantly raise cholesterol:

- Study AI424-138 followed patients taking Reyataz 300 mg, ritonavir 100 mg, tenofovir (an NRTI) 300 mg and emtricitabine (an NRTI) 200 mg. After 96 weeks, patients' mean LDL cholesterol increased only 14% from 92 mg/dL (optimal) to 105 mg/dL (near optimal).
- Study AI424-034 followed patients taking Reyataz 400 mg once daily with the fixed-dose combination: lamivudine (NRTI) 150 mg, and zidovudine (an NRTI) 300 mg twice daily. After 46 weeks, the study found no increase in mean LDL levels, which stayed constant at 98 mg/dL over the course of the study.
- Study AI424-045 followed patients taking Reyataz 300 mg once daily with ritonavir, tenofovir (an NRTI), and another NRTI. On average, patients experienced a 10% decrease in cholesterol, from 108 to 98.

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<sup>1</sup> See Third Report of the National Cholesterol Education Program Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, available at <http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm>.

114. Because Prezista causes high cholesterol, it is at a competitive disadvantage to Reyataz. This in part motivated Defendants to compete by misleadingly claiming that Prezista is lipid-neutral.

**c. J & J Misleadingly Relied on Unsubstantiated Scientific Studies to Claim Prezista is Lipid-neutral**

115. Defendants' so-called support for its "lipid-neutral" claims were two scientific studies regarding Prezista's effect on lipids which are not included in, and directly contradicted by, Prezista's label:

- The DART Study: Throughout the relevant time period, sales representatives of Defendants have relied on a study entitled "Similar Changes in Metabolic Parameters of Darunavir [Prezista] and Atazanavir [Reyataz], each Co-Administered with Low-Dose Ritonavir [Norvir] in Healthy Volunteers (TMC114-C159)" (the "DART Study") in selling and promoting Prezista to physicians.
- The Metabolik Study: Starting in 2010 and continuing until the present, sales representatives have relied on a study entitled, "METABOLIK (Metabolic Evaluation in Treatment-naïves Assessing the Impact of Two Boosted Protease Inhibitors on Lipids and Other Markers): Comparison of the Metabolic Effects of Darunavir/ritonavir [Prezista/Norvir] versus Atazanavir/ritonavir [Reyataz] over 12 weeks" (the "Metabolik Study") in selling and promoting Prezista to physicians.

116. The DART and Metabolik Studies purported to show that Prezista does not cause high cholesterol and/or high triglycerides and that Prezista is comparable to Reyataz in terms of its neutral or minimal effect on lipids.

117. Defendants engaged in off-label marketing of Prezista by downplaying the drug's dangerous effects on total cholesterol and LDL cholesterol. As discussed above, J & J engaged in off-label marketing to compete with Reyataz, a PI that does not significantly raise cholesterol. Sales representatives presented and distributed the DART study to physicians. The DART study followed 34 healthy (not HIV infected) people over a 12 week period and found similar changes

in cholesterol for persons taking Prezista and Norvir on the one hand and Reyataz and Norvir on the other. The study concluded:

Given its favorable metabolic profile and efficacy in HIV-1-infected subjects DRV/r (Prezista and Ritonovir) is a valuable therapeutic option for treatment-naïve subjects and may minimize the risk of metabolic complications.

Changes in metabolic parameters and biomarkers from baseline to Week 12 were comparable for DRV/r and ATV/r-based therapy; longer-term follow-up of these parameters is planned.

118. J & J sales representatives used this study to market Prezista as a lipid neutral PI. This marketing message was false and misleading because it was contradicted by the phase III clinical trials performed on HIV-infected patients, as opposed to healthy patients, contained on Prezista's label.

119. Both of these studies are directly contradicted by Prezista's label. Marketing Prezista as "lipid-neutral" is false and misleading because it was contradicted by the more robust, longer term, phase III clinical trials on HIV-infected patients contained in Prezista's label. The label contains evidence of efficacy based on two randomized, controlled studies comparing the safety and effectiveness of a Prezista-ritonavir combination with another PI drug combination (Kaletra-ritonavir). The one study in the label involved 192-week data from 689 patients infected with HIV and the other study involved 96-week data from 595 HIV- infected patients. In both of these studies, a clear majority of patients experienced virologic success on the Prezista-ritonavir combination, however, as noted above, a significant percentage of patients' lipid levels increased to high or very high.

120. In contrast to the clinical studies proving efficacy discussed in the label, the DART Study involved only 49 patients – all of whom were healthy and not infected with HIV. Seven of the eight authors of the study were associated with Tibotec (now known as Janssen, a

J&J subsidiary) at the time of the study. The Metabolik Study followed 65 AIDS patients for a short duration (12 weeks). Two of the authors of this study were Tibotec employees at the time the study was released. Further, Tibotec funded the Metabolik Study.

121. A subsequent article discussing 48-week results of the Metabolik Study<sup>2</sup> acknowledges the limited value of even 48-week results. Referring to the Metabolik Study as a “pilot study” intended to be “an exploratory analysis,” it states that “the small sample size and short duration of this trial limit clinical interpretation of these data.” *Id.* at 9.

**d. J & J Made Misleading Statements About the Results of the Lipid Studies**

122. Despite the limited value of the scientific studies, Defendants’ sales representatives and managers relied on them and made false and exaggerated statements about the results of these lipid studies. Relators personally heard or learned of the following misrepresentations being made to physicians by Defendants’ sales representatives on sales calls:

- Prezista is lipid neutral just like Reyataz. You will not get increase of cholesterol levels.
- Using Prezista does not affect lipids just like Reyataz.
- Patients will not see an increase in cholesterol with the use of Prezista. It is lipid neutral so it will not have an effect on cholesterol in the patient. You can expect to see the same cholesterol levels the patient had before treatment while on treatment with Prezista.
- Patients should not see any cholesterol issues whatsoever.
- Your patients all eat like crap anyway so I’m sure they already have high cholesterol so why not choose a drug that won’t make matters worse?
- Older PIs are known for increasing lipids and contributing to cardiovascular disease, with Prezista you don’t have to worry about that.

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<sup>2</sup> Aberg, Judith A. et al., “Metabolic Effects of Darunavir/Ritonavir Versus Atazanavir/Ritonavir in Treatment-Naïve, HIV Type 1-Infected Subjects over 48 Weeks”, AIDS Research and Human Retroviruses, Vol. 28, No. 00, 2012

- Patients have many risk factors that contribute to heart disease; you don't need a drug to add to the complications. By using Prezista, as shown in the DART Study, you don't have to add high cholesterol to that risk list for patients.
- HIV itself causes high cholesterol, no reason to choose a drug that also does so.
- If healthy patients saw no change you can expect to see the same results in HIV infected patients. If the drug is the culprit it would have occurred regardless of HIV status.
- Patients can expect to see only minimal increases in cholesterol levels based on this [DART] study.
- Pharmacokinetics ("PK") of the drugs prove that Reyataz increases [the effects of] Ritonavir (Norvir) [which increases lipids] and Prezista lowers it.

123. Some of the sales calls at which Relator heard or learned of these misrepresentations are detailed below in Section VI. B. 1.

2. **J & J's Overstated Claims of Superiority, Efficacy and Potency of Prezista**

124. In addition to misleadingly promoting Prezista as lipid-neutral, beginning in and around February 2007 and continuing through the present, Defendants' sales representatives and managers have made unsupported claims regarding Prezista's superiority, efficacy and potency based on its purported superior "binding affinity." All drugs in the Protease Inhibitor class of drugs work by binding to the active site of the HIV protease (an enzyme critical for viral replication) and inhibiting it, thus preventing HIV from replicating. However, Defendants' claims of superior binding affinity are misleadingly based on a clinical study of limited scientific value which is not included in the drug's FDA-approved labeling. Further, Defendants' employees falsely and misleadingly characterized the results of the study during sales calls, dinner programs and speaker programs. This binding affinity data was provided to promotional speakers in order to encourage the differentiation of Prezista and Reyataz.



i. **J & J Misleadingly Relied on an Unsubstantiated Study to Claim Superiority, Efficacy and Potency of Prezista**

125. The study is entitled “Binding Kinetics of Protease Inhibitors to Wild-Type and Multi-Drug Resistant HIV-1 Proteases: A mechanistic study of the genetic barrier to resistance of Darunavir” (hereinafter the “Binding Study”) and it was first presented (in poster format) at the 14<sup>th</sup> Conference on Retrovirus and Opportunistic Infections in Los Angeles, California on February 25-28, 2007. The Binding Study purported to compare Prezista to other Protease Inhibitor drugs (Aptivus, Agenerase, Reyataz and Kaletra) and claimed to prove that Prezista’s superior “binding affinity,” or ability of the drug to bind to the active site of the HIV protease, prevented the virus from mutating. Thus, the drug supposedly was more efficacious and potent than the other PI drugs.

126. The study is not included in the FDA-approved labeling for the drug. Its scientific value is questionable, as Tibotec (now Janssen, a J & J subsidiary) not only funded the study, but also provided the scientists who conducted it. Further, the study was performed in the lab, and not on HIV-infected patients.

ii. **The Significance of J & J’s Misleading Promotion of Prezista**

127. To understand the significance of this off-label promotion, a brief explanation of HIV/AIDS treatment is helpful. For many conditions or diseases, the patient takes one drug to adequately treat or manage the condition. For HIV/AIDS, the recommended treatment regimen is a combination of drugs because the virus is capable of changing or mutating. Fortunately, there are a whole host of anti-retroviral (ARV) drugs in various classes to choose from as treatment options. A “cocktail” of three or more ARV drugs at once can suppress the virus. However, if a patient’s disease is not controlled by ARV drugs, the virus may mutate and the patient may develop drug resistance. Drug resistance is when a drug no longer works to fight the



virus because the virus has mutated. In addition, the patient may be resistant to other drugs (even those which the patient has not yet taken may be knocked out as potential treatment options) if the virus mutates. When a patient develops resistance to one or more drugs (or an entire class of drugs), the physician must determine which drugs are still available and will still work for the patient. There are various drug-resistance tests the physician can use to help determine the patient's remaining treatment options. The real risk involved in drug resistance is treatment failure; that is, when a patient runs out of available drugs that will work to fight the virus. See <http://www.aids.org/topics/hiv-resistance-testing/>

128. Thus, claims that Prezista is a stronger drug with superior binding affinity that would prevent the virus from mutating is very important to physicians deciding which drugs to prescribe. This promotion instilled a false sense of protection that the patient would not become resistant to Prezista and the drug would continue to be effective in fighting the AIDS virus. By claiming that high binding affinity reduced the likelihood that HIV mutations would cause the drug to fail, doctors and patients were given the false illusion that Prezista would minimize chances for drug failure. This induced doctors to (1) prescribe Prezista over other PIs for treatment naive patients (patients who had not yet taken any ARV drugs) and (2) prescribe Prezista to experienced patients (patients who had already taken ARV drugs) where other PIs failed instead of switching these patients to another class of HIV drugs. In both cases, physicians' medical judgments were influenced by J & J's false statements.

129. If a patient has an HIV strain that is resistant to one drug in a three drug cocktail, it is more likely that a patient will become resistant to the other two drugs. HIV is more capable of mutating to develop resistance to two active drugs than three active drugs. By providing false assurances that HIV would not mutate to become resistant to Prezista, J & J increased the

likelihood that doctors would prescribe Prezista when it did not work, thereby increasing the likelihood that a patient's HIV would become resistant to multiple HIV drugs.

iii. **J & J Made Misleading Statements About the Results of the Binding Study**

130. J & J routinely overstated the results of the Binding Study such as Prezista's superiority to other PI drugs, its efficacy, strength, potency and durability. In promoting Prezista to physicians, J & J sales representatives and managers made unsupported representations to physicians such as the following:

- Prezista is more effective than other PIs.
- On Prezista, the patient is less likely to fail due to HIV mutations.
- Prezista can be used when patient has failed on other PIs.
- Patients won't fail on Prezista because of its binding affinity.
- Prezista's binding affinity makes it the best PI on the market.
- Prezista is the most efficacious and durable PI because of its binding affinity.
- The binding affinity puts Prezista in a class by itself. It's different from every other PI.
- Prezista stays "in the pocket" (of the HIV protease active site) leading one to believe it's a stronger, tighter binding to the receptor and therefore better for the patient so they would be less likely to fail. (Sales representatives used a visual representation to demonstrate this point by taking a fist and closing the other hand around the fist.)

Relators heard J & J representatives make the above statements to doctors and attended internal sales meetings where they were told to make such statements and give the visual representation set forth above.

iv. **J & J's Sales of Prezista Increased Significantly as a Result of the Off-Label Marketing Campaign**

131. Prezista sales increased significantly as a result of Defendants' off-label marketing campaign. As shown in the chart below, Prezista's sales increased significantly from \$150 million in 2008 to over \$500 million in 2011:

Prezista Sales:

Year	Approximate U.S. Sales
2008	\$150,000,000
2009	\$303,000,000
2010	\$401,000,000
2011	\$529,000,000

B. **Off-label Marketing of Intelence**

1. **Approved Indication of Intelence for Only Twice Daily Use Places Intelence at a Competitive Disadvantage**

132. Intelence is an NNRTI that was approved in 2008 for twice a day use ("BID") in patients who have experienced failure with other antiretroviral drugs. The dosage information on the label for Intelence states: "Adult patients: 200 mg (one 200 mg tablet or two 100 mg tablets) taken twice daily following a meal." Contrary to the label, Defendants, starting at launch in 2008, promoted and marketed the drug to be used once daily (at a double dose of 400mg once a day).

133. The fact that Intelence is approved for twice daily use places it at a competitive disadvantage with HIV drugs that have been approved for once a day use ("QD"). For example, Bristol-Myers Squibb's NNRTI, Sustiva (efavirenz), is approved to be used once a day when taken with other antiretrovirals. Doctors recognize that patients are more likely to comply with a simplified medication regime that must be taken only once a day.

134. In fact, the label for Intelence specifically warns about doubling the dose of Intelence if a patient misses a pill by more than 6 hours.

135. The label states:

If you miss a dose of INTELENCE<sup>®</sup> within 6 hours of the time you usually take it, take your dose of INTELENCE<sup>®</sup> following a meal as soon as possible. Then, take your next dose of INTELENCE<sup>®</sup> at the regularly scheduled time. **If you miss a dose of INTELENCE<sup>®</sup> by more than 6 hours of the time you usually take it, wait and then take the next dose of INTELENCE<sup>®</sup> at the regularly scheduled time.**

**Do not take more than your prescribed dose to make up for a missed dose.**  
(emphasis added).

2. **J & J Fraudulently Markets Intelence for Once a Day Use**

a. **Research Does Not Support the Use of Intelence for Once a Day Use**

136. Intelence has not been proven safe and effective for once a day use. According to the FDA Office Director memo, dose selection of Intelence in Phase III clinical trials was based on two Phase II clinical trials, TMC-125-C203 and TMC-125-C223. Both of these Phase II trials studied different doses of Intelence taken twice daily, but did not study the efficacy and safety of Intelence when taken once daily.

137. J & J used anecdotal evidence from individual doctors and small studies in making claims that Intelence was safe and effective for once-daily use.

138. For example, sales representatives touted a study of 39 patients with HIV who switched from taking Intelence twice a day to taking Intelence once a day. After only six months, the study reported no significant increase in HIV viral load. According to its conclusion, the small study merely “provided support for a larger study to investigate once daily

Intelence,” however the results were used and promoted on sales calls by representatives and managers in order to promote Intelence use once a day.

**b. J & J Makes False and Misleading Statements About Intelence**

139. Despite the lack of evidence demonstrating that Intelence was safe and effective when used once a day, J & J marketed doctors to prescribe 400mg of Intelence once a day.

140. With respect to sales calls with doctors, Relator witnessed Ms. Barnett and Mr. McSherry make the following statement regarding Intelence:

- Intelence can be used QD due to its long half-life [the rate that Intelence leaves the body].
- Intelence has been tested with QD use and patients did great! ...but J & J doesn't want to put the money behind going for a QD indication because they are launching another QD NNRTI - Edurant.
- Intelence QD can be used for dosing symmetry with the fixed dose NRTIs.
- You can start a patient on BID Intelence and once you feel comfortable they are stable, switch the patient to QD to make it easier, there are studies that have been done that are not in our package insert showing these patients did fine.

141. Doctors and physician assistants responded positively to the message:

- John Weber PA at Beth Israel Medical Center stated: Great to know, I would love to use it QD for ease of use.
- Dr. Christopher Busillo at NYU Downtown - HIV Clinic (170 William St., Manhattan) stated: I will [prescribe QD] if you think the patients will stay undetectable.
- Dr. Donald Kaminsky stated: Intelence is the best drug you guys have, thanks for the half-life info I now will use it QD.

142. Defendants' promoted Intelence for off-label uses from the time of its launch in 2008, continuing through the present. As shown in the chart below, J & J's Intelence sales have been driven upward by Defendants' fraudulently marketing the drug for off-label uses:

Intelence Sales:

Year	Approximate U.S. Sales
2010	\$127,000,000
2011	\$163,000,000

**VI. J & J'S MISLEADING AND OFF-LABEL MESSAGING WAS DELIVERED NATIONWIDE**

**A. J & J's Nationwide Sales Force was Instructed to Market Off-Label**

143. The off-label marketing of Prezista and Intelence was widespread. J & J has approximately seventy-nine sales representatives in twelve districts across the United States (New York 1, New York 2, New England, Mid-Atlantic, Chesapeake, Midwest, Florida, Mid-South, Pacific South, Pacific North, Southeast and Southwest) who market Prezista and Intelence.

144. The nationwide sales force was instructed to market off-label on "pod calls," "district calls," and "triad meetings."

145. On pod calls, two Key Account Managers ("KAMs") from different districts would conduct a talk with approximately 10-15 sales representatives from across the country. These calls were held once a month. Off-label marketing was encouraged on these calls and sales persons in different districts shared tips on how to off-label market Intelence and Prezista.

146. In fact, Relators and their respective "pod" groups each attended a meeting at Janssen headquarters in New Jersey with upper-level management. Relator Brancaccio's pod group attended in the Fall of 2010 and Relator Penelow's group in August of 2011. At both meetings, Janssen (formerly Tibotec) upper management, including the President, was in attendance and participated in the discussion. The purpose of the meeting was to discuss with the high-level management what sales strategies were working in the field and how customers

were responding. At Relator Penelow's meeting, which included among others, the President, VP of Marketing, VP of Sales, VP of Key Account Managers, VP of Human Resources, VP of Communications and the VP of Clinical, off-label marketing strategies were discussed. In discussing some of the best practices shared on the pod group calls, many individuals relayed off-label sales tactics, including promoting Prezista as lipid-neutral. Further, Relator Penelow's notes mention that she should contact KAM Nancy Bartnett to get the off-label Binding Study and lipid study to use in the field. Management essentially ignored the off-label commentary during the meeting and did not respond.

147. District calls were led by district managers and included all the salespeople in a district. Manager of New York District 1, Tony Dolisi, led these calls in Relator Penelow's district and encouraged the sales force to promote the off-label marketing messages detailed herein.

148. Triad meetings were more informal gatherings of members of the sales force within a district that frequently took place in restaurants. Relator Penelow was repeatedly urged to market off-label at these triad meetings by Dolisi and Bartnett.

149. Through these calls and meetings, J & J instructed its nationwide sales force to market off-label.

150. Relator has talked to ten current employees who have been pressured to market off-label and have in fact marketed Prezista and Intelence off-label. These sales persons marketed in New Jersey, New York, Florida, Washington DC, Maine, and California. Relator has also talked to four former employees who left J & J because they were threatened to be placed on a performance plan and were pressured to market Prezista and Intelence off-label. These persons - Russ Moyer, Lisa Cruz, Joe Holshoe and Donna Graham - were top sellers at J



& J. Joe Holshoe worked as a Senior Virology Sales Representative for J & J covering New Hampshire, but left the company when he was pressured to market off-label. He now lives in Rhode Island and works for the Navy.

151. Only sales representatives who engaged in off-label marketing were more likely to meet aggressive sales targets set by J & J. These employees, who met or exceeded their sales targets, were rewarded with promotions, bonuses and other prizes that included fully-paid vacations. One such J & J sales representative, Yvonne Wind-Vasquez – who also worked as a prescribing Physician's Assistant in Florida -- has been given numerous sales bonuses, extravagant trips and gifts for producing high sales figures, all while continuing to work in an HIV practice prescribing HIV medication. J & J ignored this conflict of interest. Ms. Wind-Vasquez and her prescribing partners have maintained the highest market share in the country. Her J & J manager, Scott Libby, has been promoted to a director's position, and has arranged to have J & J geographically realign sales districts in order to maximize bonus dollars. In accordance with his demands, Florida is now considered part of the Western region. Conversely, when Relators failed to meet their sales targets because, *inter alia*, they refused to engage in off-label marketing, they were denied promotions and bonuses.

**B. J & J Delivered the Misleading Messaging During Sales Calls, Dinner Programs and Speaker Programs**

**1. Sales Calls on Physicians**

152. J & J pressured its sale representatives to engage in off-label marketing in face to face meetings with doctors. J & J gave sales representatives multiple copies of study summaries to distribute to doctors that contained off-label claims. As set forth in detail below, sales representatives were instructed by their supervisors to use these studies to make false and misleading claims about Intelence and Prezista. To cover their tracks, the sales representatives

were told not to leave these summaries with doctors, but to retrieve them after they showed them to doctors. As sales representatives, Relators have firsthand knowledge of these facts.

153. For example, Ms. Penelow was given a binder by Sales Trainer, Tim McSherry, with studies that purportedly supported the use of Prezista and Intelence for off-label use. Ms. Barnett and Mr. McSherry encouraged Ms. Penelow to use this binder, insisting that sales persons all around the county were using a similar binder.

154. J & J's misleading messages regarding Prezista were delivered on in person sales calls, including those involving the following J & J sales representatives/ managers and physicians:

- Key Account Manager ("KAM") Nancy Barnett called on Drs. Sanjana Koshy MD, Tessa Gomez MD, John Weber PA, Nadim Salomon MD at Beth Israel Medical Center - Peter Kruger HIV Clinic (317 E. 17th St., Manhattan) whose patients are 100% Medicaid and NY State ADAP.
- KAM Nancy Barnett called on Iris Nagin PA at the Lower East Side Treatment Center (46 E. Broadway, Manhattan) whose patients are 100% Medicaid and NY State ADAP.
- KAM Nancy Barnett called on Larry Landphair PA at Astor Medical Group (67 Irving Place, Manhattan) whose patients have all types of insurance, including Medicaid and NY State ADAP.
- KAM Nancy Barnett and Tim McSherry called on Drs. Lawrence Hitzeman MD, Jean-Louis Salinas MD, Richard Gold MD at Village Care - HIV Clinic & Community Based Organization (121 W. 20th St., Manhattan) whose patients are 100% Medicaid and NY State ADAP.
- KAM Nancy Barnett and Tim McSherry called on Dr. Ricky Hsu MD at his office (154 W 14th St., Manhattan). His patients include those with all types of insurance, including Medicaid and NY State ADAP.
- KAM Nancy Barnett and Tim McSherry called on Drs. Rona Vail MD, Gal Mayer MD, Ward Carpenter MD, and Susan Weiss NP at Callen L orde Community Health Center - Lesbian/Gay/Bi-Sexual/Transgender HIV Clinic (356 W. 18th St., Manhattan) whose patients are 100% Medicaid and NY State ADAP.

- Manager of New York District 1 Tony Dolisi and Jimmy Kwok called on Dr. Andre Brutus MD at Brookdale Hospital (1 Brookdale Plaza, Brooklyn). His patients include those with all types of insurance, including about 80% Medicaid.
- Manager Tony Dolisi called on Dr. Joseph Exilhomme MD of Kings County Hospital (451 Clarkson Ave, Brooklyn). His patients include those with all types of insurance, but mainly Medicaid.
- Manager Tony Dolisi and Jimmy Kwok called on Drs. Samuel Uter MD and Joseph Paul MD at Pierre Toussaint Family Health Center (1110 Eastern Parkway, Brooklyn) whose patients include all types, including Medicare, Medicaid and NY State ADAP.
- KAM Nancy Bartnett and Manager Tony Dolisi called on Drs. David Rubin MD and Sorana Segal-Maurer MD at New York Hospital Queens - HIV Clinic (138-47 Horace Harding Expwy, 2nd Fl, Queens) whose patients are 100% Medicaid and NY State ADAP.
- Manager Tony Dolisi and Jimmy Kwok called on Dr. Sangam Jhaveri MD at Queens Long Island Medical Group (18005 Hillside Ave, Queens) whose patients included all types, including Medicare, Medicaid, and NY State ADAP.
- Manager Tony Dolisi and Jimmy Kwok called on Alla Shkolnik NP (42 Hausman St, Brooklyn) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.
- Manager Tony Dolisi and Jimmy Kwok called on Kathleen Aratoon NP (8268 164th St, Queens) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.
- KAM Nancy Bartnett called on Dr. Alexander McMeeking MD and Abbe Friedberg NP (110 E. 40th St., Manhattan) whose patients include all types, including Medicare, Medicaid, and NY State ADAP.
- KAM Nancy Bartnett called on Dr. Michael Mullen MD, Chief Medical Director at Mt. Sinai - Jack Martin HIV Clinic (5 E. 98th St., Manhattan) whose patients include 100% Medicaid and NY State ADAP.
- KAM Nancy Bartnett called on Dr. Christopher Busillo at NYU Downtown - HIV Clinic (170 William St., Manhattan) whose patients include about 80% Medicaid and NY State ADAP.
- KAM Nancy Bartnett and Manager Tony Dolisi called on Dr. Donald Kaminsky at his office (10 Union Sq. East, Manhattan). His patients include some Medicaid patients.

155. J & J's misleading messages regarding Intelence were delivered in sales calls, including those involving the following J & J sales representatives/ managers and physicians:

- KAM Nancy Bartnett and Tim McSherry called on Dr. Ricky Hsu at his office (154 W 14th St., Manhattan). His patients include Medicaid and NY State ADAP patient.
- KAM Nancy Bartnett and Tim McSherry called on Dr. Rona Vail and Dr. Gal Mayer at the Lorde Community Health Center – Lesbian/Gay/Bi-Sexual/Transgender HIV Clinic (356 W. 18th St., Manhattan). Their patients are all Medicaid and NY State ADAP patients.
- KAM Nancy Bartnett called on Dr. Sanjana Koshy, Dr. Tessa Gomez, and Dr. Nadim Salomon at Beth Israel Medical Center - Peter Kruger HIV Clinic (317 E. 17th St., Manhattan). Their patients are Medicaid and NY State ADAP patients.
- Manager Tony Dolisi and Jimmy Kwok called on Dr. Andre Brutus at Brookdale Hospital (1 Brookdale Plaza, Brooklyn). His patients include Medicaid patients.
- Manager Tony Dolisi called on Dr. Joseph Exilhomme at Kings County Hospital (451 Clarkson Ave, Brooklyn). His patients include Medicaid patients.
- Manager Tony Dolisi and Jimmy Kwok called on Drs. Samuel Uter MD and Joseph Paul MD at Pierre Toussaint Family Health Center (1110 Eastern Parkway, Brooklyn). Their patients include Medicare, Medicaid, and NY State ADAP patients.
- KAM Nancy Bartnett and manager Tony Dolisi called on Dr. David Rubin and Sorana Segal-Maurer at New York Hospital Queens - HIV Clinic (138-47 Horace Harding Expwy, 2nd Fl, Queens). Their patients are Medicaid and NY State ADAP patients.
- Manager Tony Dolisi and Jimmy Kwok called on Sangam Jhaveri MD at Queens Long Island Medical Group (18005 Hillside Ave, Queens). His patients include Medicare, Medicaid, and NY State ADAP.
- Nancy Bartnett called on Donald Kaminsky MD at his private practice (10 Union Sq. East, Manhattan). His patients include Medicaid patients.
- KAM Nancy Bartnett, Jimmy Kwok, and Christine Brancaccio called on Dr. Carlos Salama at Elmhurst Hospital (79-01 Broadway, Elmhurst). His patients are predominantly Medicare, Medicaid and NYS ADAP.

156. For physician sales calls, J & J gave its sales representatives copies of the studies to rely on when calling on physicians, even though the studies are not included in the drug's package insert or approved by the FDA. Managers and supervisors pressured the sales force to show these studies to doctors to promote Intelence and Prezista off-label. The sales force, including Relators, was specifically instructed not to follow official company policy that disallowed the distribution of these studies to doctors. For example, Mr. Dolisi (manager) and Ms. Barnett (KAM), Relators' direct supervisors, provided Relators the studies referenced herein and encouraged Relators to discuss these studies with doctors.

157. Furthermore, in around March 2012, Mr. Dolisi told his sales force to "be creative outside the label" when marketing Prezista and Intelence.

158. In fact, when doctors had scientific and medical questions about Prezista and Intelence, the sales force, including Relators, were instructed by Ms. Barnett not to route calls to J & J's scientific liaison, but rather to Ms. Barnett herself, who would falsely claim that she was the scientific liaison and repeat the false and misleading marketing messages.

159. Within Relators' district (NY 1), Ms. Barnett and Mr. Dolisi freely used the studies during sales calls to physicians. They frequently showed the studies to physicians, sometimes leaving the studies at the physicians' offices, and sometimes sending them electronically.

160. KAM Barnett bragged to Relator Penelow about her off-label sales calls in an attempt to convince Relator to do the same. When Relator Penelow voiced her discomfort, she was in turn demoted and taken off key initiatives. KAM Barnett bragged to Relator Brancaccio that the off-label marketing was making a great impact with and resonating with physicians. To demonstrate, she referenced a physician she routinely called on, Dr. Segal-Maurer, who had a

54% market share of Prezista prescriptions within all ARV drugs, and a 57.5% market share within the PI class.

161. As recently as November 13, 2012, on a sales call on Dr. Glenn Turrett, a physician at New York Hospital Queens, Ms. Barnett falsely minimized the risk of Prezista increasing a patient's lipids. She stated, "from a lipid standpoint, they [Reyataz and Prezista] are both the same" when in fact, as discussed above, this is untrue as Reyataz does not raise cholesterol, as Prezista does.

**1. Dinner Programs**

162. In addition to sales calls, J & J fraudulently promoted Prezista off-label at dinner programs by overstating their superiority to other drugs based on their so-called binding affinity and their alleged favorable lipid profile and fraudulently promoted Intelence off-label for once a day use. These dinner programs initially started as a mere thank you for high volume sellers, but eventually morphed into a well-attended educational dinner. Ms. Barnett distributed a slide deck for speakers to use at dinner programs that included a slide reprinting Figure 2 from the Binding Study. Figure 2 purportedly demonstrates in graph form the much stronger binding affinity of Prezista than the other PI drugs included in the study.

163. Oftentimes, J & J would plant questioners in the audience of these dinner presentations in order to ensure that off-label use of the drugs was a topic of discussion. Some health care provider attendees who asked off-label questions included the following: Dr. Michael Mullen, Dr. Nadim Salomon, Dr. Donald Kaminsky, Dr. Gal Mayer, Larry Higgins and John Weber PA and Mark Miller RN. This tactic disguised that J & J organized the speaker events for the purpose of engaging in off-label marketing.



164. J & J's misleading promotion regarding Prezista concerning the favorable lipid profile and the binding affinity were delivered during the following dinner programs:

- January 27<sup>th</sup>, 2010 – A dinner program at Bond Street Restaurant in New York, NY featured a promotional speech by Dr. Sorana Segal-Maurer, who was instructed by Key Account Manager Nancy Barnett to sell Prezista on the uniqueness and favorable binding ability of Prezista. Ms. Barnett placed Mark Miller in the audience to bring up questions regarding the off-label uses of the drug during the question and answer session that followed. Attendees included: Bina Berkovich, PA, Dr. Daniel Bowers, Dr. Krisczar Bungay, Key Account Manager Reggie Cadet, Edwin Calderon, PA, District Manager Tony Dolisi, Mohammed Eritonui, Dr. Avisheh Forouzesh, Dr. Stuart Haber, Vanessa Haney, Dr. Joanna Kopacz, Eric Leach, NP, Dr. Paul Mathieu, Dr. Gal Mayer, Sales Trainer Tim McSherry, Mark Miller, RN, Erik Mortensen, NP, Iris Nagin, NP, Dr. Anita Radix, Dr. Joseph Rahimian, Dr. Sireesha Reddy, Access and Reimbursement Director Eric Sherr, Dr. Rashmi Singh, Senior Virology Sales Specialist Steve Smacchia, Dr. Celestine Tchikounzi, Carl Urban, Ph.D., Dr. Rona Vail, Dr. Wehbeh Wehbeh, and Mulubrhan Zewde, NP.
- February 23<sup>rd</sup>, 2010 – A dinner program at Fleming's Steak House in Raleigh, NC featured a promotional speech by Dr. Segal-Maurer.
- March 30<sup>th</sup>, 2010 – A dinner program at Joe's Stone Crab in Miami Beach, FL featured a promotional speech by Dr. Segal-Maurer, who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels.
- April 13<sup>th</sup>, 2010 – A dinner program at Acquarello in San Francisco, CA featured a promotional speech by Dr. Segal-Maurer, who promoted information off-label concerning Prezista's effect on lipid levels.
- April 14<sup>th</sup>, 2010 – A dinner program at BLD Restaurant in Los Angeles, CA featured a promotional speech by Dr. Segal-Maurer.
- April 14<sup>th</sup>, 2010 – A dinner program at Cecconi's in West Hollywood, CA featured a promotional speech by Dr. Segal-Maurer.
- May 12<sup>th</sup>, 2010 – A dinner program at Serenade in Chatham, NJ featured a promotional speech by Dr. Segal-Maurer.
- June 28<sup>th</sup>, 2010 – A dinner program at Capital Grille in Chicago, IL featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's effect on lipid levels.
- August 10<sup>th</sup>, 2010 – A dinner program at Steinhilber's Restaurant in Virginia Beach, VA featured a promotional speech by Dr. Segal-Maurer.



- October 7<sup>th</sup>, 2010 – A dinner program at Porter House in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity. Attendees included: Sherly Altidor, PA, Dr. Lloyd Bailey, Dr. Ronald Grossman, Peter Harz, Thomas Hayden, Geraldine Joseph, PA, Sales Trainer Tim McSherry, Dr. Michael Morelli, Senior Virology Sales Representative Dennis O'Keeffe, Brad Rothenbuhler, Dr. Antonio Urbina, Keith Wills, PA, Barbara Zagelbaum, Mulubrhan Zewde, NP, and Stuart Zuckerman, RPH.
- November 30<sup>th</sup>, 2010 – A dinner program at Citrone in Redlands, CA featured a promotional speech by Dr. Segal-Maurer.
- February 1<sup>st</sup>, 2011 – A dinner program at Aldea Restaurant in New York, NY featured a promotional speech by Dr. Seagl-Maurer who promoted information off-label concerning Prezista's effect on lipid levels. Attendees included: KAM Nancy Bartnett, Dr. Robert Chavez, District Manager Tony Dolisi, Dr. Michael Gaisa, Dr. Jeffrey Greene, Dr. Lawrence Hitzeman, Dr. Donald Kaminsky, Dr. Martin Markowitz, Dr. Alexander McMeeking, Sales Trainer Tim McSherry, Dr. Michael Mullen, Relator Jessica Penelow, Dr. Jean-Louis Salinas, and Senior Virology Sales Specialist Steve Smacchia.
- May 4<sup>th</sup>, 2011 – A dinner program at Carltun on the Park in East Meadow, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity, stating that it staying in the pocket longer than any other PI drug, and effect on lipid levels, favorably comparing it to Reyataz. Attendees included: KAM Nancy Bartnett, Relator Christine Brancaccio, John Civitello, RN, Dr. Karl Deshrage, Al Dossantos, RPH, Dr. Steven Golinowski, Dr. Sabiha Haque, and Debbie Tirelli.
- October 24<sup>th</sup>, 2011 – A dinner program at TreDici in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels. Attendees included: Jocquain Arcena, KAM Nancy Bartnett, Dr. Rita Chow, Dr. Gaisa, Dr. Livette Johnson, Dr. Barbara Johnston, Dr. Oscar Klein, Dr. Luz Amarilis Lugo, Sales Trainer Tim McSherry, Mark Miller, RN, Janet Parker, Dr. John Steever, and Dr. Glenn Turett.
- November 2<sup>nd</sup>, 2011 – A dinner program at Alpha Fusion in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Nancy Bartnett, Dr. Adrian Demidont, Dr. Orin Douglas, Erin Mazza, PA, Ronica Mukerjee, NP, Steve Rodgers, NP, Dr. Urbina, and Susan Weiss, NP.
- November 2<sup>nd</sup> 2011 – A dinner program at Tamarind in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's binding affinity and effect on lipid levels. Attendees included: Joaquin Arcena, KAM Nancy Bartnett, Monique Carasso, NP, Molly

Cronin, PA, Reyna Cruz, Dr. Tessa Gomez, Dr. Haber, Vanessa Haney, Sales Trainer Tim McSherry, Mark Miller, RN, Dr. Mullen, Dr. Salinas, and Senior Virology Sales Specialist Steve Smacchia.

- January 17, 2012 – A dinner program at Aldea Restaurant in New York, NY featured a promotional speech by Dr. Segal-Maurer who promoted information off-label concerning Prezista's effect on lipid levels. Attendees included: KAM Nancy Bartnett, Dr. Bungay, Dr. Ward Carpenter, Dr. Chavez, Dr. Stephen Dillon, Dr. Kaminsky, Dr. McMeeking, Dr. Mullen, Realtor Jessica Penelow, Susanne Rendeiro, NP, Dr. Nadim Salomon, and Senior Virology Sales Specialist Steve Smacchia.
- January 25<sup>th</sup>, 2012 – A dinner program at TreDici in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: Nancy Bartnett, Jocquain Aracena, Reyna Cruz, Dr. Johnson, Dr. Klein, Sales Trainer Tim McSherry, Mark Miller, RN, Janet Parker, Access and Reimbursement Director Eric Sherr, Maria Sires, Senior Virology Sales Specialist Steve Smacchia, Elizabeth Smith, PA, and Dr. Turett.
- February 23<sup>rd</sup>, 2012 – A dinner program at Morton's Steakhouse in Bethesda, MD featured a promotional speech by Dr. Segal-Maurer. Attendees included: Dr. Jose Chavez and Dr. Veronica Jenkins.
- February 29<sup>th</sup>, 2012 – A dinner program at Capital Grille in Tampa, FL featured a promotional speech by Dr. Segal-Maurer.
- March 1<sup>st</sup>, 2012 – A dinner program at Ristorante Claretta in Palm City, FL featured a promotional speech by Dr. Segal-Maurer.
- March 12<sup>th</sup>, 2012 – A dinner program at Le Vallauris in Palm Springs, CA featured a promotional speech by Dr. Segal-Maurer.
- April 5<sup>th</sup>, 2012 – A dinner program at Estia Restaurant in Philadelphia, PA featured a promotional speech by Dr. Segal-Maurer. Attendees included: Susan Daniluk, Rob Mascaro, Key Account Manager Robert Mumford, David Agosto, NP, David Downie, Sales Representative Ed Duca, Sheila Henry, Bertha Jackson, NP, Angela Kapalko, PA, Mable Lyons, and Christine Randazzo, RN.
- June 13<sup>th</sup>, 2012 – A dinner program at Rathbun's in Atlanta, GA featured a promotional speech by Dr. Segal-Maurer.

165. J & J's misleading messages regarding Intelence were delivered during the following dinner programs:

- April 22<sup>nd</sup>, 2010 – A dinner program at Novita in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Nancy Bartnett, Dr. Gaisa, Dr. Hitzeman, Lawrence Landphair, NP, Dr. Todd McNiff, Sales Trainer Tim McSherry, Mark Miller, RN, Dr. Mullen, Dr. Salinas, Dr. William Shay, and Dr. Wehbeh.
- September 22<sup>nd</sup>, 2010 – A dinner program at Blue Water Grill in New York, NY featured a promotional speech by Dr. Donald Kaminsky who promoted information off-label concerning the half-life of Intelence. Attendees included: KAM Nancy Bartnett, Dr. Chavez, Dr. Bowers, Michelle Patton, and Realtor Jessica Penelow.
- September 22<sup>nd</sup>, 2010 – A dinner program at Blue Water Grill in New York, NY featured a promotional speech by Dr. Kaminsky who promoted using Intelence once a day, and stated that it was the only NNRTI he was currently administering. Attendees included KAM Nancy Bartnett, Dr. Chavez, Dr. Bowers, Michelle Patton, Relator Jessica Penelow, and Susan Santoro.
- November 11<sup>th</sup>, 2010 – a dinner program at Philip Marie in New York, NY featured a promotional speech by Dr. Kaminsky who promoted the once a day use of Intelence, and discussed its off-label uses. Attendees included: KAM Nancy Bartnett, Dr. Leonidez De Guzman, Dr. Gweneth Francis, Dr. Robert Goldstein, Dr. Gomez, Dr. Sanjana Koshy, Sondra Middleton, PA, Dr. Akshay Manohar, Relator Jessica Penelow, Dr. Salomon, Dr. Usha Mathur-Wagh, and John Weber, RPA.
- November 11<sup>th</sup>, 2010 – A dinner program at Philip Marie in New York, NY featured a promotional speech by Dr. Kaminsky who promoted information off-label concerning the half-life of Intelence. Attendees included: KAM Nancy Bartnett, Dr. De Guzman, Dr. Francis, Dr. Goldstein, Dr. Gomez, Dr. Koshy, Sondra Middleton, PA, Dr. Monohar, Relator Jessica Penelow, Dr. Salomon, Dr. Mathur-Wagh, and John Weber, RPA.
- December 7<sup>th</sup>, 2010 – A dinner program at Spice Market in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Nancy Bartnett, Dr. Bungay, Dr. Carpenter, Dr. Dillon, Lawrence Landphair, NP, Dr. Mayer, Sales Trainer Tim McSherry, Dr. Radix, and Susan Weiss, NP.
- December 8<sup>th</sup>, 2010 – A dinner program at Morton's Steakhouse in Great Neck, NY featured a promotional speech by Dr. Kaminsky who discussed information off-label including using Intelence once a day. Attendees included: KAM Nancy Bartnett, Relator Christine Brancaccio, Dr. Patricia Cole, Dr. Deshrage, Dr. Rachel Franck, Lulette Infante, RN, Jean Jacques, Regina Mengual, Martine Michel-Toure, David Natal, Joseph Navarra, RPH, Steven Orandello, Jack Pierro, Dr. Christine Sethna, Access and Reimbursement Director Eric Sherr, Marvin Siegel, Daniel Velazquez, and Suzanne Vento, RN.

- December 14<sup>th</sup>, 2010 – A dinner program at Spice Market in New York, NY featured a promotional speech by Dr. Kaminsky who promoted information off-label concerning using Intelence once a day. Attendees included: Dr. Leonard Berkowitz, Key Account Manager Reggie Cadet, Gregory Celestin, PA, Agnes Cha, and Senior Virology Sales Specialist Angelica Edwards.
- February 10<sup>th</sup>, 2011 – A dinner program at Morton's Steakhouse in Brooklyn, NY featured a promotional speech by Dr. Kaminsky. Senior Virology Sales Representative Jimmy Kwok also spoke and promoted off-label uses. Attendees included: Dr. Jamsheed Abadi, Dr. Lubin Augustin, Dr. Andre Brutus, Key Account Manager Reggie Cadet, District Manager Tony Dolisi, Senior Virology Sales Specialist Angelica Edwards, Rebecca Fry, NP, Dr. Jesi Ramone, and Alla Shkolnik, NP.
- April 26<sup>th</sup>, 2011 – A dinner program at Pera in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Dr. Yusuf Afacan, Key Account Manager Reggie Cadet, Senior Virology Sales Representative Jimmy Kwok, Dr. Tevfik Menten, Valerie Santangelo, NP, Alla Shkolnik, NP, and Dr. Mathur-Wagh.
- July 27<sup>th</sup>, 2011 – A dinner program at Spanish Tavern in Newark, NJ featured a promotional speech by Dr. Segal-Maurer who stated that Intelence could be used successfully once a day, and that she used it successfully this way in her own practice. Attendees included: Dr. Muhammad Afridi, Dr. Spartaco Bellomo, Sophie Ciszewski, RN, Rickey Danszey, Susan Garcia, Lillie Jones, Sandy Lenflin, Maria Lorenzo, Dr. Lewis Marton, Vieshia Morales, Veronica Naranso, Executive Virology Sales Representative Bryan O'Dea, Senior Virology Sales Representative Dennis O'Keeffe, Veronica Osero, Nancy Peterson, Dr. Lauro Rocha, Dominick Varsalone, RN, Keith Williams, and Kim Worrell.
- August 11<sup>th</sup>, 2011 – A dinner program at Novita in New York, NY featured a promotional speech by Dr. Segal-Maurer who discussed using Intelence once a day. Attendees included: KAM Nancy Bartnett, Lara Comotoa, Dr. Mayer, Sales Trainer Tim McSherry, Dr. Mullen, Dr. Radix, Dr. Jilan Shah, Dr. Belinda Velazquez, and Susan Weiss, NP.
- March 26<sup>th</sup>, 2012 – A dinner program at Tre Dici in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Joquain Arcena, KAM Nancy Bartnett, Reyna Cruz, Dr. Gaisa, Dr. Johnson, Dr. Klein, Dr. Lugo, Mark Miller, RN, Janet Parker, Relator Jessica Penelow, Senior Virology Sales Specialist Steve Smacchia, Eliyahith Smith, and Dr. Glenn Turrett.

## 2. Speaker Programs

166. J & J also paid high-prescribing physicians to give speeches fraudulently marketing Prezista and Intelence to a crowd of physicians in other settings. These speaker programs provide opportunities for J & J to hire individuals to speak on the off-label uses of their drugs. The speakers are paid upwards of \$2,500 per talk, and are shuttled on all-expenses-paid trips across the country. They are often sent to other states not only to promote off-label, but also to accommodate their personal travel destinations: Dr. Sorana Segal-Maurer frequently asks to be sent to Chicago to watch baseball with her son or to California to shop with her daughter, Dr. Nadim Solomon prefers to be sent to Florida to visit family, etc.

167. Nancy Bartnett, Executive Key Account Manager at J & J, organized these speaker programs. She would recruit doctors that she knew were willing to market Prezista and Intelence off-label. She would then prepare slide decks for these speakers with off-label marketing messages and send these doctors around the country to promote Prezista and Intelence off-label. Nancy would then prepare the speakers by telling them what to expect, who would be in attendance, and inform the speaker to share their anecdotal experience with the drug. These speakers earned significant fees from J & J. If an individual was considered a high volume prescriber, they would be added to the list of speakers. Conversely, if they failed to reach a certain percentage, they were removed under the guise that they did not have enough patient experience. Dr. Juan Bailey from Beth Israel Medical Center was removed from the list because of his low market share and his unwillingness to promote the off-label studies. MedForce manages J & J's speaker fund and maintains records of who attends the programs, who are the speakers, and how much money is paid.

168. As with dinner programs, J & J would plant questioners in the audience during the question and answer session which would usually follow the one-hour presentation, to ask questions about the off-label use of the drug. This tactic disguised that J & J organized the speaker events for the purpose of engaging in off-label marketing.

169. Moreover, J & J paid speakers, including Drs. Segal-Maurer, Hsu, Kaminsky, Brutus, Salomon and Rashbaum to give speeches across the United States which included off-label messages regarding Prezista. Ms. Barnett provided these speakers with the same slide deck including the Binding Study slide, as the one used by the dinner program speakers.

170. For example, J & J paid Dr. Ricky Hsu approximately \$50,000 – \$70,000 a year for speeches occurring all over the country (with a per speech payment of approximately \$2,000-\$2,500). Further, Dr. Segal-Maurer most likely received at least \$50,000 per year for the last six years of speeches on behalf of J & J. Dr. Bruce Rashbaum is paid approximately \$2,500 per program, and is currently slotted for nineteen programs this year. Dr. Rashbaum is an important figure for J & J as he is also a patient of the drugs, and discloses that information during his presentations.

171. J & J's misleading messages regarding Prezista were delivered during the following speaker programs:

- February 23<sup>rd</sup>, 2010 – A speaker program at East Carolina University in Greenville, NC featured a promotional speech by Dr. Segal-Maurer who focused on differentiating Prezista from other PIs with regard to its binding affinity and effect on lipid levels.
- June 30<sup>th</sup>, 2010 – A speaker program at Provient Hospital in Chicago, IL featured a promotional speech by Dr. Segal-Maurer.
- November 30<sup>th</sup>, 2010 – A speaker program at Orion Health Group in Palm Springs, CA featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's effect on lipid levels.



- December 9<sup>th</sup>, 2010 – A speaker program at Liberty Health Center in Jersey City, NJ featured a promotional speech by Dr. Segal-Maurer.
- December 10<sup>th</sup>, 2010 – A speaker program at Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Segal-Maurer who discussed how lipid friendly Prezista is for aging patients, and how it stays in the pocket longer and is more forgiving if a patient misses a dose. Attendees included: Relator Christine Brancaccio, Victor Cruz, Dr. Nyabilondi Ebama, Susan Kiernan, Dr. Kopacz, Noriel Mariano, Dr. David Rubin, Thema Tierney, and Dr. Wehbeh.
- March 16<sup>th</sup>, 2011 – A speaker program at SouthWest CARE Center in Santa Fe, NM featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's favorable lipid profile. Attendees included: Dr. Betsy Brown, Dr. Warren Goldenberg, Dr. Trevor Hawkins, Cyatha Lujan, LPN, Peter Mengazo, Anthony Mueller, Luc Poppe, Senior Virology Sales Representative Brendan Snyder, Jeff Thomas, Larry Turner, and Wenoah Veikley, RN.
- February 14<sup>th</sup>, 2012 – A speaker program at Sunset Terrace Family Health Center in Brooklyn, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: KAM Reggie Cadet, Misty Chiu, NP, Dr. Deeptha Nedunchezian, Graciele Phlatts, LPN, and Jonathan Reynolds.
- February 23<sup>rd</sup>, 2012 – A speaker program at Montgomery County Health Department in Silver Springs, MD featured a promotional speech by Dr. Segal-Maurer. Attendees included Dr. Anthony Fernandez.
- February 29<sup>th</sup>, 2012 – A speaker program at Consultative Medicine at Daytona Beach, FL featured a promotional speech by Dr. Segal-Maurer.
- March 12<sup>th</sup>, 2012 – A speaker program at Desert AIDS Project in Palm Springs, CA and featured a promotional speech by Dr. Segal-Maurer.
- March 23<sup>rd</sup>, 2012 – A speaker program at Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Segal-Maurer who discussed Prezista's effect on lipid levels. Attendees included: Lilia Albaneze, Relator Christine Brancaccio, Karen Lau, PA, Susan Kiernan, Dr. Nauman Piracha, Javeria Shakil, Dr. Peter Wasserman, and Dr. Sadia Zahid.
- April 5<sup>th</sup>, 2012 – A speaker program at Atlantic City Outpatient Clinic in Atlantic City, NJ featured a promotional speech by Dr. Segal-Maurer. Attendees included: Dr. Ricardo Barzaga, Terrence Crowley, Deb Downey, Jean Freeman, Anaris Gonzalez, Jean Haspel, NP, Dr. Dana Jones, Mike Khan, Christine McGloin, KAM Robert Mumford, Nana Noal, Cathy Stapleton, LPN, and Kay Wilsbach.
- April 12<sup>th</sup>, 2012 – A speaker program at Avia in Savannah, GA featured a promotional speech by Dr. Segal-Maurer.



172. J & J's misleading messages regarding Intelence were delivered during the following speaker programs:

- March 18<sup>th</sup>, 2010 – A speaker program at Queens HIV Care Network in Jamaica, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Dr. Sandra Alvarez, KAM Nancy Bartnett, Stephen Cerny, Dr. Jennifer Chung, Brenda Collins, Janice Daste Sinkler, Francisco Diaz, NP, Andres Garcia, Dr. Deborah Greene, Michael Hadley, Delores Henley, Myung Hunt, Sonia Kaikai, Rosemary Lopez, Virginia Morales, Judy Pedraza, Gustavo Pedroza, Carin Pinney, Hector Resto, Melissa Robertson, RN, Nataly Rubio Torres, Janice Sickler, Robert Steptoe, and Michael Valentin.
- May 12<sup>th</sup>, 2010 – A speaker program at Village Center New York in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees were all social workers and included: KAM Nancy Bartnett, Daniel Calderon, PA, Steven Deitch, Karen Ford, Lois Gonzalez, Michael Hickey, RPH, Dr. Tiffany Le, Denise Mahon, RN, Ken Moberg, NP, Patricia Motus, OTR, Kelly Nicely, Bernice Noriega, Juan Olmedo, Maria Palanachud, Carmen Rodriguez, Danielle Sullivan, Joanne Tehrani, RD, Lisa Torres, and Dr. Janice Zimmerman.
- June 3<sup>rd</sup>, 2010 – A speaker program at West Midtown Medical Group in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Nancy Bartnett, Dr. Philip Gianelli, Kathryn Godly, PA, Daniel Painagua, PA, Dr. Steven Rappaport, Marianne Sciberras, Linda Soo, RN, and Blair Wiggins, PA.
- October 7<sup>th</sup>, 2010 – A speaker program at Town Total in New York, NY featured a promotional speech by Dr. Kaminsky who discussed using Intelence once a day. Attendees included: Heather Baek, KAM Nancy Bartnett, Lisa Boodram, Bernice Chen, PHAR, Fernando De Los Santos, PHAR, Michael Escuder, RPH, Aisha Heslop, Tasmiya Khan, PHAR, Hening Kwan, PHAR, Sam Merrill, Joseph Navaro, Michael Navaro, John Navarra, RPH, Joseph Navarra, RPH, Lynn Navarra, Mariya Rockman, Dr. Marvin Siegal, Usha Tejueaney, Dr. Cindy Wang, Lingyee Wong, Allison Yee, PHAR, and Irina Yusim, PHAR.
- October 15<sup>th</sup>, 2010 – A speaker program at NYHQ Special Care Clinic in Flushing, NY featured a promotional speech by Dr. Trevor Hawkins. Attendees included: KAM Nancy Bartnett, Relator Christine Brancaccio, Victor Cruz, Dr. Ebama, Lydia Gonzalez, Karen Hall, Susan Kiernan, Dr. Kopacz, Noriel Mariano, Dr. Rubin, Dr. Segal-Maurer, Dr. Tchikounzi, Theme Tierney, Dr. Wasserman, and Dr. Wehbeh.
- October 28<sup>th</sup>, 2010 – A speaker program at West Midtown Medical Center in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Katherine Godly, PA, Dr. Patricia Grosvenor, Yasmine Hubbard, Daniel Paniagua,

PA, Dr. Rappaport, Marianne Riberras, Senior Virology Sales Specialist Steve Smacchia, and Blair Wiggins, P.A..

- October 29<sup>th</sup>, 2010 –A speaker program at Lutheran Medical Center in Brooklyn, NY featured a promotional speech by Dr. Kaminsky. Attendees included: Gabriel Bananeo, Dr. Laura Beauchamps Bonnet, KAM Reggie Cadet, Dalila Dieppa, Dr. David John, Katherine O'Neil, Alan Orfel, Dr. Marcelo Venegas-Pizarro, and Tielei Wong.
- November 11<sup>th</sup>, 2010 – A speaker program at Greenwich House in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Nancy Bartnett, Gloria Diaz, Judy Goris, Tracy Henry, PT, Veronica Martinez, R Membo Mcanell, Melissa Nordstrom, Judy Pedroza, Dr. Punyadech Photangtham, Louis Rayas, Susanne Rendeiro, NP, Angelica Rolon, and Alexandra Schaumber, MSW.
- December 7<sup>th</sup>, 2010 – A speaker program at Greewich House in New York, NY featured a promotional speech by Dr. Segal-Maurer. Attendees included: Madeline Bellamy, Nicholas Calabrese, Gloria Davey, Judy Goris, Michael Hickey, RPH, George Jagatic, MS, Lee La Shore, Dr. Le, Denise Mahon, RN, Veronica Martinez, Ken Moberg, NP, Melissa Nordstrom, Susanne Rendeiro, NP, Carmen Rodriguez, Annette Scantebury, Senior Virology Sales Specialist Steve Smacchia, and Ilsa Torres.
- March 10<sup>th</sup>, 2011 – A speaker program at Lutheran Sunset Park Health Center in Brooklyn, NY featured a promotional speech from Dr. Kaminsky. Attendees included: Dr. Beauchamps Bonnet, Senior Virology Sales Specialist Angelica Edwards, Rebecca Fry, NP, Gloria Ivonne Moreno, Katherine O'Neil, Jason Siegel, ArronTorrel, and Dr. Marcelo Venegas Pizarro.
- July 27<sup>th</sup>, 2011 – A speaker program at Village Day Treatment in New York, NY featured a promotional speech by Dr. Kaminsky. Attendees included: KAM Nancy Bartnett, Jay Dismukes, Veronica Gernett, MS, Michael Hickey, RPH, Kevin Hook, Denise Mahon, RN, Ken Moberg, NP, Kelly Nicely, CRNA, Bernice Noriega, Juan Olmeda, MSW, Amy Panichi, Carmen Rodriguez, Joanne Tehrani, RD, Lisa Torres, and Dr. Zimmerman.
- October 6<sup>th</sup>, 2011 – A speaker program at Newark Community Health Center in East Orange, NJ featured a promotional speech by Dr. Kaminsky who promoted using Intelence once a day. Attendees included: Latifah Abdus-solaen, Dr. Sebastian Kabiawu, Executive Virology Sales Representative Bryan O'Dea, O Ogunno, Nancy Peterson, and Sheila Roymono.

C. **J & J Fails to Meaningfully Investigate Complaints of Salespeople Pressured to Engage In Off-Label Marketing**

173. In and around 2010, a New Jersey sales representative, Joanne Cesario, complained to upper management about Frank Murphy, her supervisor, pressuring her to use off-label marketing materials provided by J & J to market Prezista and Intelence to doctors. As discussed above, J & J had provided sales representatives with studies that would assist them in marketing Prezista and Intelence off-label, but J & J's official policy – which sales persons were expected to deviate from – prevented distribution of these materials.

174. In response, J & J conducted a perfunctory investigation. Upon information and belief, each sales representative for the New Jersey office was called in to a meeting with attorneys and asked if they illegally marketed drugs off-label or were pressured to do so. The representatives met with one another and decided to protect Mr. Murphy by denying the allegations. In doing so, they ended the investigation.

175. Currently, neither Ms. Cesario nor Mr. Murphy is working for J & J.

176. J & J continued its practice of providing sales representatives with materials to assist in the off-label marketing of Prezista and Intelence.

VII. **FALSE CLAIMS**

A. **Defendants Caused the Submission of False Claims for Misbranded and Off-Label Prezista and Intelence Prescriptions**

177. Throughout the relevant time period, Defendants knowingly caused the submission of false claims for reimbursement of Prezista and Intelence. As alleged in detail above, during sales calls with physicians, dinner program and speaker programs nationwide, Defendants marketed Prezista and Intelence in a false and misleading way by minimizing a serious side effect associated with Prezista (increases lipids), overstating Prezista's efficacy (the

Binding Study) and falsely claiming that Intelence is safe and effective taken once-a-day. This conduct illegally misbranded the drug<sup>3</sup> and constituted off-label promotion.

178. As a result of Defendants' misleading messages regarding Prezista and Intelence, Defendants caused false claims to be submitted to the Government Healthcare Programs for reimbursement. Each of the claims for Prezista and Intelence included an express and/or implied certification of compliance with federal and state law and regulations. Those certifications were false because the drugs were misbranded in violation of the FDCA and/or off-label.

179. While the cost of providing Prezista and Intelence for on-label and non-misbranded uses to Government Healthcare Program recipients is covered by the Government Healthcare Programs, including Medicare and Medicaid, the cost of off-label and misbranded prescriptions is not. Since Prezista and Intelence were promoted off-label and misbranded, claims for prescriptions caused by this misconduct are not reimbursable.

180. Knowingly submitting or causing the submission of claims for prescription drugs which are not reimbursable creates liability under the FCA. Thus, these claims to the government for reimbursement caused to be submitted by Defendants' unlawful conduct constitute violations of section 3729 of the FCA and relevant State FCAs.

**B. Defendants Caused the Submission of False Claims in Violation of the Anti-Kickback Statute**

181. Defendants' payments to physicians for dinner and speaker programs which included misleading and off-label messages regarding Prezista and Intelence as well as other remuneration provided the means for Defendants to pay kickbacks to physicians to induce

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<sup>3</sup> Again, a drug is "misbranded" if its labeling (defined very broadly) and advertising is false and misleading in any way.

prescriptions of Prezista and Intelence. Any prescriptions for Prezista and Intelence written by said physicians during the relevant time period were tainted by these kickbacks.

182. Additionally, Defendants caused claims to be submitted to the Government Healthcare Programs for reimbursement. Each of the claims for Prezista and Intelence included an express and/or implied certification of compliance with federal and state law and regulations. Those certifications were false because they were in violation of the AKS. Further, since 2010, the AKS now expressly states that a violation of the AKS constitutes a “false or fraudulent” claim under the False Claims Act. (42 U.S.C. § 1320(a)-7b(g)).

183. Further, compliance with the AKS is a material condition of payment under Medicare and Medicaid.<sup>4</sup> Falsely certifying compliance with a condition of payment, or causing another to falsely certify compliance with a condition of payment, incurs liability under the FCA.<sup>5</sup>

184. Thus, the claims to the Government Healthcare Programs caused to be submitted by Defendants’ unlawful conduct constitute violations of section 3729 of the FCA and relevant State FCAs.

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<sup>4</sup> See *United States et al. ex rel. Westmoreland v. Amgen Inc.*, 2011 U.S. App. LEXIS 15036 (1st Cir. July 22, 2011); *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 2011 U.S. App. LEXIS 10972 (1st Cir. June 1, 2011); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States ex rel. Conner v. Salina Regional Health Ctr.*, 543 F.3d 1211, 1223 n.8 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1259-1260 (11th Cir. 2005); *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

<sup>5</sup> *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 2011 U.S. App. LEXIS 10972, \*36 (1st Cir. June 1, 2011) (“unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party”); see also *United States v. Rivera*, 55 F.3d 703, 710-712 (1st Cir. 1995) (stating that a “false claim may be presented through an innocent third party” (citations omitted)).

**VIII. COUNTS**

**COUNT I**

**FEDERAL FALSE CLAIMS ACT,  
31 U.S.C.A. §§ 3729(a)(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

185. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

186. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by the Government Healthcare Programs. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to the United States in violation of Section 3729(a)(1)(A) of the Act.

187. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to the United States, in violation of Section 3729(a)(1)(B) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

188. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT II**

**FEDERAL FALSE CLAIMS ACT,**  
**31 U.S.C. § 3729(a)(1)(A)**  
**FOR UNLAWFUL KICKBACKS**

189. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

190. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value, such as free trips, for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to the Government Healthcare Programs constituted a false or fraudulent claim for payment.

191. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to the United States in violation of Section 3729(a)(1)(A) of the Act.

192. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT III**

**CALIFORNIA FALSE CLAIMS ACT**  
**CAL. GOV'T CODE §§ 12651(A)(1), (2)**  
**FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS**  
**OF PREZISTA AND INTELENCE**

193. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



194. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by California. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to California in violation of Section 12651(a)(1) of the Act.

195. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to California, in violation of Section 12651(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

196. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to California in violation of 12651(a)(1) and (2) of the Act.

197. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT IV**

#### **CALIFORNIA FALSE CLAIMS ACT** **Cal. Gov’t Code § 12651(a)(1)** **FOR UNLAWFUL KICKBACKS**

198. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

199. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to California constituted a false or fraudulent claim for payment.

200. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to California in violation of Section 12651(a)(1) of the Act.

201. As a result of Defendants' knowing violations of the Act, California has sustained actual damages.

#### **COUNT V**

#### **COLORADO MEDICAID FALSE CLAIMS ACT C.R.S.A. §§ 25.5-4-305(1)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

202. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

203. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Colorado. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) of the Act.

204. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Colorado, in violation of Section 25.5-4-

305(1)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

205. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) and (1)(b) of the Act.

206. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

### **COUNT VI**

#### **COLORADO MEDICAID FALSE CLAIMS ACT** **C.R.S. § 25.5-4-305(1)(a)** **FOR UNLAWFUL KICKBACKS**

207. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

208. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Colorado constituted a false or fraudulent claim for payment.

209. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Colorado in violation of Section 25.5-4-305(1)(a) of the Act.

210. As a result of Defendants' knowing violations of the Act, Colorado has sustained actual damages.

**COUNT VII**

**CONNECTICUT FALSE CLAIMS ACT  
CONN. GEN. STAT. ANN. §§ 17B-301B(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

211. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

212. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Connecticut. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 17b-301b(a)(1) of the Act.

213. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, has knowingly made or used false records or statements material to false or fraudulent claims to Connecticut, in violation of Section 17b-301b(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

214. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 17b-301b(a)(1) and (a)(2) of the Act.

215. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT VIII**

**CONNECTICUT FALSE CLAIMS ACT**  
**CONN. GEN. STAT. § 17B-301b(a)(1)**  
**FOR UNLAWFUL KICKBACKS**

216. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

217. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Connecticut constituted a false or fraudulent claim for payment.

218. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Connecticut in violation of Section 17B-301b(a)(1) of the Act.

219. As a result of Defendants' knowing violations of the Act, Connecticut has sustained actual damages.

**COUNT XL**

**DELAWARE FALSE CLAIMS AND REPORTING ACT  
DEL CODE ANN. TIT. 6, §§ 1201(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

220. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

221. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Delaware. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) of the Act.

222. Further, throughout the relevant time period, Defendants through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Delaware, in violation of Section 1201(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

223. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) and (a)(2) of the Act.

224. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT X**

**DELAWARE FALSE CLAIMS AND REPORTING ACT**

**Del Code Ann. Tit. 6, §§1201(a)(1)**

**FOR UNLAWFUL KICKBACKS**

225. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

226. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Delaware constituted a false or fraudulent claim for payment.

227. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Delaware in violation of Section 1201(a)(1) of the Act.

228. As a result of Defendants' knowing violations of the Act, Delaware has sustained actual damages.

**COUNT XI**

**FLORIDA FALSE CLAIMS ACT**

**FLA. STAT. ANN. §§ 68.082(2)(A), (B)**

**FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

229. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



230. Throughout the relevant time period, Defendants caused submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Florida. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) of the Act.

231. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Florida, in violation of Section 68.082(2)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

232. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) and (2)(b) of the Act.

233. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

## **COUNT XII**

### **FLORIDA FALSE CLAIMS ACT** **Fla. Stat. Ann. §§68.082(2)(a)** **FOR UNLAWFUL KICKBACKS**

234. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

235. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Florida constituted a false or fraudulent claim for payment.

236. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 68.082(2)(a) of the Act.

237. As a result of Defendants' knowing violations of the Act, Florida has sustained actual damages.

### **COUNT XIII**

#### **GEORGIA FALSE MEDICAID CLAIMS ACT GA. CODE ANN. §§ 49-4-168.1(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

238. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

239. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Georgia. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Georgia in violation of Section 49-4-168.1(a)(1) of the Act.

240. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Georgia, in violation of Section 49-4-

168.1(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

241. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Florida in violation of Section 49-4-168.1(a)(1) and (a)(2) of the Act.

242. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XIV**

**GEORGIA FALSE MEDICAID CLAIMS ACT**  
**Ga. Code Ann. §§ 49-4-168.1(a)(1)**  
**FOR UNLAWFUL KICKBACKS**

243. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

244. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Georgia constituted a false or fraudulent claim for payment.

245. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Georgia in violation of Section 49-4-168(a)(1) of the Act.

246. As a result of Defendants' knowing violations of the Act, Georgia has sustained actual damages.

**COUNT XV**

**HAWAII FALSE CLAIMS ACT  
HAW. REV. STAT. §§ 661-21(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

247. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

248. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Hawaii. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

249. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Hawaii, in violation of Section 661-21(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

250. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

251. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT XVI**

**HAWAII FALSE CLAIMS ACT**  
**Haw. Rev. Stat. §661-21(a)(1)**  
**FOR UNLAWFUL KICKBACKS**

252. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

253. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Hawaii constituted a false or fraudulent claim for payment.

254. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Hawaii in violation of Section 661-21(a)(1) of the Act.

255. As a result of Defendants' knowing violations of the Act, Hawaii has sustained actual damages.

**COUNT XVII**

**ILLINOIS FALSE CLAIMS ACT  
740 IL.C.S. §§ 175/3(A)(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

256. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

257. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Illinois. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Illinois in violation of Section 175/3(a)(1)(A) of the Act.

258. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Illinois, in violation of Section 175/3(a)(1)(B) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

259. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to payment to Illinois in violation of Section 175/3(a)(1)(A) and (B) of the Act.

260. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XVIII**

**ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT**

**740 Ill. Comp. Stat. §§175/3(a)(1)(A)**  
**FOR UNLAWFUL KICKBACKS**

261. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

262. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Illinois constituted a false or fraudulent claim for payment.

263. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Illinois in violation of Section 175/3(a)(1)(A) of the Act.

264. As a result of Defendants' knowing violations of the Act, Illinois has sustained actual damages.

**COUNTY XIX**

**INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT**

**IND. CODE ANN. §§ 5-11-5.5-2(B)(1), (2)**  
**FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS**  
**OF PREZISTA AND INTELENCE**

265. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



266. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Indiana. Through this conduct, Defendant knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) of the Act.

267. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Indiana, in violation of Section 5-11-5.5-2(b)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

268. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) and (2) of the Act.

269. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT XX**

#### **INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT**

#### **Ind. Code Ann. §§5-11-5.5-2(b)(1)** **FOR UNLAWFUL KICKBACKS**

270. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

271. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Indiana constituted a false or fraudulent claim for payment.

272. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Indiana in violation of Section 5-11-5.5-2(b)(1) of the Act.

273. As a result of Defendants' knowing violations of the Act, Indiana has sustained actual damages.

#### **COUNTY XXI**

#### **IOWA FALSE CLAIMS ACT IOWA CODE ANN. § 685.2(1)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

274. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

275. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Iowa. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(a) of the Act.

276. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Iowa, in violation of Section 685.2(1)(b) of

the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

277. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(a) of the Act.

278. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

### **COUNT XXII**

#### **IOWA FALSE CLAIMS ACT IOWA CODE ANN. § 685.2(1)(A) FOR UNLAWFUL KICKBACKS**

279. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

280. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Iowa constituted a false or fraudulent claim for payment.

281. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Iowa in violation of Section 685.2(1)(A) of the Act.

282. As a result of Defendants' knowing violations of the Act, Iowa has sustained actual damages.

**COUNT XIII**

**LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW  
LA. REV. STAT. ANN. §§ 46:438.3(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

283. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

284. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Louisiana. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

285. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Louisiana, in violation of Section 46:438.3(B) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

286. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

287. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT XXIV**

**LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW**

**La. Rev. Stat. §46:438.3(A)**  
**FOR UNLAWFUL KICKBACKS**

288. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

289. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Louisiana constituted a false or fraudulent claim for payment.

290. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Louisiana in violation of Section 46:438.3(A) of the Act.

291. As a result of Defendants' knowing violations of the Act, Louisiana has sustained actual damages.

**COUNT XXV**

**THE MARYLAND FALSE HEALTH CLAIMS ACT  
MD. CODE ANN., HEALTH-GEN. §§ 2-602(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

292. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

293. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Maryland. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Maryland in violation of Section 2-602(a)(1) of the Act.

294. Further, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Maryland, in violation of Section 2-602(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

295. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Maryland in violation of Section 2-602(a)(1) and (a)(2) of the Act.

296. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XXVI**

**THE MARYLAND FALSE HEALTH CLAIMS ACT**  
**MD. CODE ANN. §§ 2-602(a)(1)**  
**FOR UNLAWFUL KICKBACKS**

297. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

298. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Maryland constituted a false or fraudulent claim for payment.

299. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Maryland in violation of Section 2-602(a)(1) of the Act.

300. As a result of Defendants' knowing violations of the Act, Maryland has sustained actual damages.

**COUNT XVII**

**MASSACHUSETTS FALSE CLAIMS LAW**  
**MASS. GEN. LAWS ANN. CH. 12 §§ 5B(1), (2)**  
**FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS**  
**OF PREZISTA AND INTELENCE**

301. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



302. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Massachusetts. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) of the Act.

303. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Massachusetts, in violation of Section 5B(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

304. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) and (2) of the Act.

305. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT XXVII**

#### **MASSACHUSETTS FALSE CLAIMS LAW Mass. Gen. Laws ch. 12 §§5B(1) FOR UNLAWFUL KICKBACKS**

306. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

307. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Massachusetts constituted a false or fraudulent claim for payment.

308. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Massachusetts in violation of Section 5B(1) of the Act.

309. As a result of Defendants' knowing violations of the Act, Massachusetts has sustained actual damages.

#### **COUNT XXIX**

#### **MICHIGAN MEDICAID FALSE CLAIMS ACT MICH. COMP. LAWS. §§ 400.607(2), (3) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

310. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

311. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Michigan. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(2) of the Act.

312. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Michigan, in violation of Section

400.607(3) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

313. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(2) of the Act.

314. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XXX**

**MICHIGAN MEDICAID FALSE CLAIMS ACT  
Mich. Comp. Laws. §§400.607(1)  
FOR UNLAWFUL KICKBACKS**

315. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

316. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Michigan constituted a false or fraudulent claim for payment.

317. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Michigan in violation of Section 400.607(1) of the Act.

318. As a result of Defendants' knowing violations of the Act, Michigan has sustained actual damages.

**COUNT XXXI**

**THE MINNESOTA FALSE CLAIMS ACT  
MINN. STAT. ANN. §§ 15C.02(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

319. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

320. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Minnesota. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) of the Act.

321. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Minnesota, in violation of Section 15C.02(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

322. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) and (a)(2) of the Act.

323. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT XXXII**

**THE MINNESOTA FALSE CLAIMS ACT  
Minn. Stat. §§15C.02(a)(1)  
FOR UNLAWFUL KICKBACKS**

324. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

325. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Minnesota constituted a false or fraudulent claim for payment.

326. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Minnesota in violation of Section 15C.02(a)(1) of the Act.

327. As a result of Defendants' knowing violations of the Act, Minnesota has sustained actual damages.

**COUNT XXXIII**

**MONTANA FALSE CLAIMS ACT  
MONT. CODE ANN. §§ 17-8-403(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

328. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

329. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Montana. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

330. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Montana, in violation of Section 17-8-403(1)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

331. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

332. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XXXIV**

**MONTANA FALSE CLAIMS ACT  
Mont. Code Ann. § 17-8-403(1)(a)  
FOR UNLAWFUL KICKBACKS**

333. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

334. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Montana constituted a false or fraudulent claim for payment.

335. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Montana in violation of Section 17-8-403(1)(a) of the Act.

336. As a result of Defendants' knowing violations of the Act, Montana has sustained actual damages.

**COUNT XXXV**

**THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL  
GOVERNMENT ACT  
NEV. REV. STAT. ANN. §§ 357.040(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

337. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



338. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Nevada. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

339. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Nevada, in violation of Section 357.040(1)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

340. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

341. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

### **COUNT XXXVI**

#### **THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT**

#### **Nev. Rev. Stat. Ann. §§357.040(1)(a) FOR UNLAWFUL KICKBACKS**

342. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

343. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Nevada constituted a false or fraudulent claim for payment.

344. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Nevada in violation of Section 357.040(1)(a) of the Act.

345. As a result of Defendants' knowing violations of the Act, Nevada has sustained actual damages.

#### **COUNT XXXVII**

#### **NEW HAMPSHIRE FALSE CLAIMS ACT N.H. REV. STAT. ANN. §§ 167:61-B(I)(A), (B) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

346. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

347. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by New Hampshire. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Hampshire in violation of Section 167:61-b(I)(a) of the Act.

348. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to New Hampshire, in violation of Section 167:61-b(I)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

349. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Hampshire in violation of Section 167:61-b(I)(a) of the Act.

350. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT XXXVIII**

#### **NEW HAMPSHIRE FALSE CLAIMS ACT N.H. Rev. Stat. Ann. §§167:61-b(I)(a) FOR UNLAWFUL KICKBACKS**

351. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

352. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New Hampshire constituted a false or fraudulent claim for payment.

353. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Hampshire in violation of Section 167:61-b(I)(a) of the Act.

354. As a result of Defendants' knowing violations of the Act, New Hampshire has sustained actual damages.

**COUNT XXXIX**

**NEW JERSEY FALSE CLAIMS ACT  
N.J. STAT. ANN. §§ 2A:32C-3(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

355. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

356. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by New Jersey. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

357. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to New Jersey, in violation of Section 2A:32C-3(b) of the Act. Defendant has knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

358. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

359. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT XL**

**NEW JERSEY FALSE CLAIMS ACT  
N.J. Stat. § 2A:32C-3(a)  
FOR UNLAWFUL KICKBACKS**

360. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

361. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New Jersey constituted a false or fraudulent claim for payment.

362. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Jersey in violation of Section 2A:32C-3(a) of the Act.

363. As a result of Defendants' knowing violations of the Act, New Jersey has sustained actual damages.

**COUNT XLI**

**NEW MEXICO FRAUD AGAINST TAXPAYERS ACT  
N.M. STAT. ANN. §§ 27-14-4 (A), (C)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

364. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

365. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by New Mexico. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) of the Act.

366. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to New Mexico, in violation of Section 27-14-4(C) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

367. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) and (C) of the Act.

368. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XLII**

**NEW MEXICO FRAUD AGAINST TAXPAYERS ACT  
N.M. Stat. Ann. §§27-14-4 (A)  
FOR UNLAWFUL KICKBACKS**

369. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

370. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New Mexico constituted a false or fraudulent claim for payment.

371. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New Mexico in violation of Section 27-14-4(A) of the Act.

372. As a result of Defendants' knowing violations of the Act, New Mexico has sustained actual damages.

**COUNT XLIII**

**NEW YORK FALSE CLAIMS ACT  
N.Y. STATE FIN. LAW §§ 189(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

373. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



374. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by New York. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) of the Act.

375. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to New York, in violation of Section 189(1)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

376. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) and (1)(b) of the Act.

377. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT XLIV**

#### **NEW YORK FALSE CLAIMS ACT N.Y. State Fin. §§189(1)(a) FOR UNLAWFUL KICKBACKS**

378. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

379. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to New York constituted a false or fraudulent claim for payment.

380. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to New York in violation of Section 189(1)(a) of the Act.

381. As a result of Defendants' knowing violations of the Act, New York has sustained actual damages.

**COUNT XLV**

**NORTH CAROLINA FALSE CLAIMS ACT  
N.C. GEN. STAT. ANN. §§ 1-607(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

382. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

383. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by North Carolina. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

384. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to North Carolina, in violation of Section 1-

607(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

385. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

386. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT XLVI**

**NORTH CAROLINA FALSE CLAIMS ACT  
2009-554 C. SESS. LAWS § 1-607(a)(1)  
FOR UNLAWFUL KICKBACKS**

387. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

388. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to North Carolina constituted a false or fraudulent claim for payment.

389. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to North Carolina in violation of Section 1-607(a)(1) of the Act.

390. As a result of Defendants' knowing violations of the Act, North Carolina has sustained actual damages.

**COUNT XLVII**

**OKLAHOMA MEDICAID FALSE CLAIMS ACT  
OKLA. STAT. ANN. TIT. 63 §§ 5053.1(B)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

391. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

392. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Oklahoma. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Oklahoma in violation of Section 5053.1(B)(1) of the Act.

393. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Oklahoma, in violation of Section 5053.1(B)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

394. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to klahoma in violation of Section 5053.1(B)(1) and (B)(2) of the Act.

395. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT XLVIII**

**OKLAHOMA MEDICAID FALSE CLAIMS ACT  
Okla. Stat. tit. 63 §§5053.1(B)(1)  
FOR UNLAWFUL KICKBACKS**

396. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

397. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Oklahoma constituted a false or fraudulent claim for payment.

398. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Oklahoma in violation of Section 5053.1(B)(1) of the Act.

399. As a result of Defendants' knowing violations of the Act, Oklahoma has sustained actual damages.

**COUNT XLIX**

**RHODE ISLAND FALSE CLAIMS ACT  
R.I. GEN. LAWS ANN. §§ 9-1.1-3(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

400. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

401. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Rhode Island. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) of the Act.

402. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Rhode Island, in violation of Section 9-1.1-3(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

403. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) and (a)(2) of the Act.

404. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

**COUNT L**

**RHODE ISLAND FALSE CLAIMS ACT  
R.I. Gen. Laws § 9-1.1-3(a)(1)  
FOR UNLAWFUL KICKBACKS**

405. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

406. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Rhode Island constituted a false or fraudulent claim for payment.

407. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Rhode Island in violation of Section 9-1.1-3(a)(1) of the Act.

408. As a result of Defendants' knowing violations of the Act, Rhode Island has sustained actual damages.

**COUNT LI**

**TENNESSEE MEDICAID FALSE CLAIMS ACT  
TENN. CODE ANN. §§ 71-5-182(A)(1)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

409. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



410. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Tennessee. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(a)(1)(A) of the Act.

411. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Tennessee, in violation of Section 71-5-182(a)(1)(B) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

412. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(a)(1)(A) and (B) of the Act.

413. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

### **COUNT LII**

#### **TENNESSEE MEDICAID FALSE CLAIMS ACT Tenn. Code Ann. §§71-5-182(1)(A) FOR UNLAWFUL KICKBACKS**

414. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

415. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with

dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Tennessee constituted a false or fraudulent claim for payment.

416. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Tennessee in violation of Section 71-5-182(1)(A) of the Act.

417. As a result of Defendants' knowing violations of the Act, Tennessee has sustained actual damages.

### **COUNT LIII**

#### **TEXAS MEDICAID FRAUD PREVENTION LAW TEX. HUM. RES. CODE ANN. §§ 36.002(1), (4) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

418. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

419. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Texas. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

420. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Texas, in violation of Section 36.002(4) of

the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

421. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

422. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT LIV**

**TEXAS MEDICAID FRAUD PREVENTION LAW  
Tex. Hum. Res. Code Ann. §§36.002(1)  
FOR UNLAWFUL KICKBACKS**

423. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

424. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Texas constituted a false or fraudulent claim for payment.

425. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Texas in violation of Section 36.002(1) of the Act.

426. As a result of Defendants' knowing violations of the Act, Texas has sustained actual damages.

**COUNT LV**

**VIRGINIA FRAUD AGAINST TAXPAYERS ACT  
VA. CODE ANN. §§ 8.01-216.3(A)(1), (2)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

427. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

428. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Virginia. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) of the Act.

429. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Virginia, in violation of Section 8.01-216.3(A)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

430. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) and (A)(2) of the Act.

431. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT LVI**

**VIRGINIA FRAUD AGAINST TAXPAYERS ACT  
Va. Code Ann. §§8.01-216.3(A)(1)  
FOR UNLAWFUL KICKBACKS**

432. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

433. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Virginia constituted a false or fraudulent claim for payment.

434. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Virginia in violation of Section 8.01-216.3(A)(1) of the Act.

435. As a result of Defendants' knowing violations of the Act, Virginia has sustained actual damages.

**COUNT LVII**

**WASHINGTON HEALTH CARE FALSE CLAIM ACT  
WASH. REV. CODE §§ 48.80.030(1), (2), AND (3)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

436. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

437. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Washington. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Washington in violation of Sections 48.80.030(1) and 48.80.030(2) of the Act.

438. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Washington in violation of Section 48.80.030(3) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is "lipid-neutral," Prezista has superior "binding affinity" over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

439. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Washington in violation of Sections 48.80.030(1) and 48.80.030(2) of the Act.

440. As a result of Defendants' knowing violations of the Act, the United States has sustained actual damages.

**COUNT LVIII**

**WASHINGTON HEALTH CARE FALSE CLAIM ACT  
Wash. Rev. Code §§ 48.80.030(1)  
FOR UNLAWFUL KICKBACKS**

441. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

442. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Washington constituted a false or fraudulent claim for payment.

443. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Washington in violation of Section 48.80.030(1) of the Act.

444. As a result of Defendants' knowing violations of the Act, Washington has sustained actual damages.

**COUNT LIX**

**WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT  
WIS. STAT. ANN. §§ 20.931(2)(A), (B)  
FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS  
OF PREZISTA AND INTELENCE**

445. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.



446. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by Wisconsin. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Wisconsin in violation of Section 20.931(2)(a) of the Act.

447. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to Wisconsin, in violation of Section 20.931(2)(b) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

448. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Wisconsin in violation of Section 20.931(2)(a) and (2)(b) of the Act.

449. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

#### **COUNT LX**

#### **WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT Wis. Stat § 20.931(2)(a) FOR UNLAWFUL KICKBACKS**

450. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

451. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to Wisconsin constituted a false or fraudulent claim for payment.

452. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to Wisconsin in violation of Section 20.931(2)(a) of the Act.

453. As a result of Defendants' knowing violations of the Act, Wisconsin has sustained actual damages.

#### **COUNT LXI**

#### **DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE §§ 2-381.02(A)(1), (2) FOR MISBRANDED AND OFF-LABEL PRESCRIPTIONS OF PREZISTA AND INTELENCE**

454. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

455. Throughout the relevant time period, Defendants caused the submission of false claims for reimbursement for Prezista and Intelence. These claims were false because claims for misbranded drugs and/or claims submitted due to off-label promotion are not eligible for reimbursement by District of Columbia. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-381.02(a)(1) of the Act.

456. Further, throughout the relevant time period, Defendants, through its off-label marketing and misbranding of Prezista and Intelence, have knowingly made or used false records or statements material to false or fraudulent claims to the District of Columbia, in violation of Section 2-381.02(a)(2) of the Act. Defendants have knowingly made numerous misleading statements, false statements, and omissions regarding Prezista and Intelence, including but not limited to the claim that Prezista is “lipid-neutral,” Prezista has superior “binding affinity” over other protease inhibitor drugs, and Intelence is safe and effective for once a day use.

457. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-381.02(a)(1) and (a)(2) of the Act.

458. As a result of Defendants’ knowing violations of the Act, the United States has sustained actual damages.

### **COUNT LXII**

#### **DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. Code Ann. §§2-308.14(a)(1) FOR UNLAWFUL KICKBACKS**

459. Relators reallege and incorporate by reference the preceding paragraphs as if fully set forth herein.

460. Throughout the relevant time period, Defendants have knowingly and willfully made unlawful payments to physicians and other healthcare professionals in connection with dinner and speaker programs and provided other things of value for the purpose of, among other things, inducing them to prescribe Prezista and Intelence, payment for which may be made in whole or in part under the Government Healthcare Programs. Each claim tainted by these unlawful kickbacks which was subsequently presented to District of Columbia constituted a false or fraudulent claim for payment.

461. Through this conduct, Defendants knowingly caused false or fraudulent claims for payment to District of Columbia in violation of Section 2-308.14(a)(1) of the Act.

462. As a result of Defendants' knowing violations of the Act, District of Columbia has sustained actual damages.

### **REQUESTS FOR RELIEF**

WHEREFORE, Relator, on behalf of the United States and the Plaintiff States, demands that judgment be entered in his favor and against Defendants for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes, with respect to the Federal False Claims Act, three times the amount of damages to the Federal Government plus civil penalties of no more than Eleven Thousand Dollars (\$11,000.00) and no less than Five Thousand Five Hundred Dollars (\$5,500.00) for each false claim, and any other recoveries or relief provided for under the Federal False Claims Act.

This Request also includes, with respect to the state statutes cited above, the maximum damages permitted by those statutes and the maximum fine or penalty permitted by those statutes, and any other recoveries or relief provided for under the State FCA's.

Further, Relator requests that he receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

### **DEMAND FOR JURY TRIAL**

A jury trial is demanded in this case.

Dated: December 18, 2012

Respectfully submitted,

/s/ Peter S. Pearlman

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*Attorneys for Plaintiff Relators*

### CERTIFICATE OF SERVICE

I, Joy Clairmont, hereby certify that the Complaint pursuant to the Federal False Claims Act, 31 U.S.C. §§3729 Et Seq. and Pendent State False Claims Act was filed on December 18, 2012 with the Clerk of Court and sent to the following parties by certified mail, return receipt requested:

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*/s/Joy P. Clairmont*

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